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# MEDICAL DEVICES AND THE VETERANS ADMINISTRATION

## A TECHNICAL MEMORANDUM

FEBRUARY 1985

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CONGRESS OF THE UNITED STATES
**Office of Technology Assessment**
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# Preface

This technical memorandum is part of a larger assessment of Federal policies and the medical devices industry, requested by the Senate Committee on Labor and Human Resources. In its endorsement of the overall assessment, the Senate Committee on Veterans' Affairs requested the Office of Technology Assessment (OTA) to address specifically the activities of the Veterans Administration (VA) regarding device development and procurement. The VA is an important provider of medical devices and services for diagnosis, treatment, and rehabilitation of the veteran population.

OTA found that the VA's current system of medical device-related research, development, evaluation, procurement, and use has a number of weaknesses. Better analytical methods for evaluating and procuring the most appropriate devices at least cost could be applied at various points in technology development and use. In addition, VA research and development, evaluation, and procurement could be better integrated. Several new VA programs and committees may improve the evaluation and procurement processes and help to integrate the functions, especially the purchase of major new medical technologies.

Valuable guidance was provided by the advisory panel for the OTA assessment on *Federal Policies and the Medical Devices Industry,* chaired by Richard R. Nelson, Professor of Economics, Yale University. A large number of persons in the VA and in the medical devices industry were consulted. John C. Langenbrunner, analyst, is the principal author of this technical memorandum. Other key OTA staff involved in its development were Cynthia P. King, Katherine E. Locke, and Jane E. Sisk.

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[1] From December 1983.
[2] Until November 1983.
[3] Until January 1984.

# Glossary of Acronyms

AMVETS—American Veterans of World War II, Korea, and Vietnam
BVA —Blinded Veterans Association
CID —Commercial Item Description
CT —computed tomography
DAV —Disabled American Veterans
DM&S —Department of Medicine and Surgery
DOD —Department of Defense
DRGs —diagnosis-related groups
ETIP —Experimental Technology Incentives Program
FDA —Food and Drug Administration, Department of Health and Human Services
FSS —Federal Supply Schedule
GAO —General Accounting Office
GRECC —Geriatric Research, Education, and Clinical Centers
HSR&D —Health Services Research and Development Service
MEDIPP —Medical District Initiated Program Planning
MR&A —Marketing Research and Analysis
NAS —National Academy of Sciences
NMR —nuclear magnetic resonance
NSO —National Service Officer
OTA —Office of Technology Assessment
PSAS —Prosthetics and Sensory Aids Service
PTEC —Prosthetic Technology Evaluation Committee
PVA —Paralyzed Veterans of America
R&D —research and development
Rehabilitation R&D— Rehabilitation Research and Development Service
T&E —Testing and Evaluation Staff
VA —Veterans Administration
VAMKC —VA Marketing Center
VAPC —VA Prosthetics Center
VFW —Veterans of Foreign Wars of the United States

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# Chapter 1

# Introduction and Summary

Chapter 1

# Introduction and Summary

## BACKGROUND AND SCOPE OF THIS STUDY

Many medical devices have been developed in recent years, and medical practice has changed accordingly, lengthening and improving the lives of American people.[1] In serving its special population, the Veterans Administration (VA) is one increasingly important provider of these sophisticated medical devices and services for diagnosis, treatment, and rehabilitation.

This technical memorandum was prepared as part of OTA's assessment of *Federal Policies and the Medical Devices Industry*, conducted at the request of the Senate Committee on Labor and Human Resources, with the endorsement of the Senate Committee on Veterans' Affairs. The memorandum responds specifically to the Senate Committee on Veterans' Affairs request for information on the VA's role in device development and procurement.

The VA health care delivery system is now the largest in the Nation, with 172 medical centers, 98 nursing homes, 16 domiciliaries, and 226 outpatient clinics.[2] [3] The VA employs the full-time equivalent of almost 200,000 physicians, dentists, nurses, and administrative and support personnel. An estimated 30 million veterans are eligible for its health care services, and the VA supports a full range of these services. These same characteristics make the VA an excellent setting for evaluating medical devices and technologies (109,118).

Since the late 1940s the VA has been an important source of research and development funds, especially for rehabilitative technologies and devices. The VA evaluates new equipment for safety and technical performance. Its Office of Procurement and Supply buys many medical devices; its medical facilities acquired nearly $1.3 billion in equipment and supplies in fiscal year 1982 alone.[4] The VA is also a significant part of the market for devices such as prosthetics and wheelchairs that are designed for disabled people. In addition, other organizations, such as the Department of Defense, refer to the VA's supply catalog in making procurement decisions.

This technical memorandum emphasizes internal VA policies and procedures related to medical devices. It provides information from three different perspectives: that of the veteran as a consumer, that of the device industry as a supplier, and that of the VA itself. Topics addressed, for example, include the VA's effect on private research and development and decisionmaking more generally.

Research in the biomedical sciences, such as physiology and anatomy, provides the knowledge to develop diagnostic, preventive, and therapeutic devices. However, much of the basic research that leads to these devices is also performed in such fields as physics, chemistry, and electronics. This situation makes the creation and production of devices especially complex and difficult to analyze (7).

Nonetheless, several stages of technological development and diffusion can be identified. Initially, the results of basic and applied research are consulted in preparing specifications and building prototype devices (fig. 1). The next stages, refining the prototype for marketing and testing its safety, reliability, and performance, may be even more costly and lengthy than developing the prototype. Following development, facilities for manufacturing the device must be planned and constructed, and marketing efforts begun. Finally, devices are manufactured, purchased, and used.

---

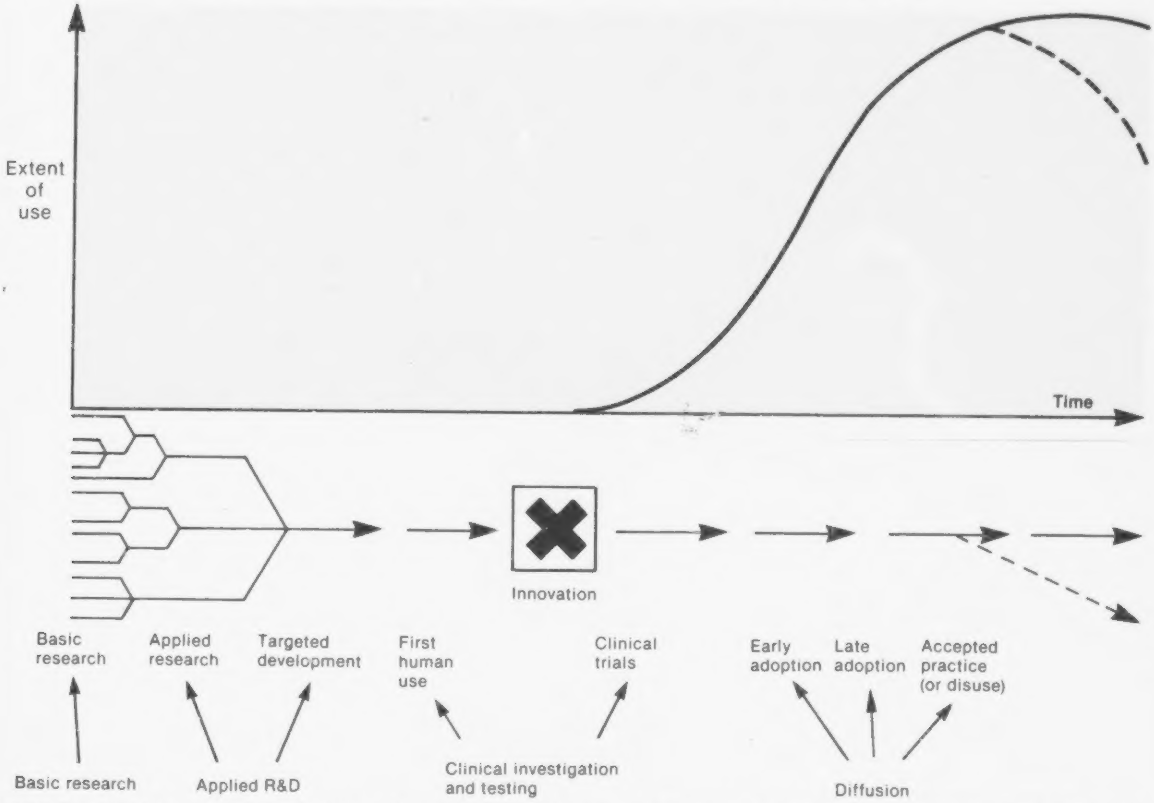
[1] Medical devices encompass an enormous variety of supplies and equipment, from frequently purchased inexpensive items, such as bandages and syringes, to infrequently purchased expensive ones, such as clinical laboratory and imaging equipment. In this study the definition of a medical device is taken from the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act (Public Law 94-295). They define a medical device as any instrument, apparatus, or other similar or related article that is intended to prevent, diagnose, mitigate, or treat disease or to affect the structure or function of the body. Drugs, which achieve their effects through chemical action within the body, are separately defined.

[2] Many VA medical facilities are actually self-sustaining communities, with a medical center, power plant, restaurant, fire department, garage, warehouse, movie theater, library, pharmacy, apartments, recreation areas, and business offices—with all the needs that these facilities require to operate. Medical facility purchases of equipment and supplies, therefore, also include items and services that cannot be strictly classified as medical devices (146).

[3] The Hospital Corp. of America, a private, "for-profit" hospital chain, has more facilities, but accounts for revenues only about half the size of the VA's health care delivery budget (32).

[4] Domiciliaries are homes where food, clothing, and necessary medical services are provided to ambulatory veterans.

**Figure 1.—The Development and Diffusion of Medical Technologies**



SOURCE: Office of Technology Assessment, *Development of Medical Technology: Opportunities for Assessment* (Washington, DC: U.S. Government Printing Office, stock No. 052-003-00217-5, August 1976), as amended.

## SUMMARY

### Veterans and the VA Health Care Delivery System

Among congressionally mandated benefits are health care services for eligible veterans. Eligibility determination is complex but in brief, veterans with service-connected disabilities and veterans with non-service-connected disabilities who are unable to obtain or pay for needed medical care are both eligible for rehabilitative and other comprehensive medical services. Several other groups of veterans have been declared eligible for VA health care benefits without being unable to pay: those age 65 and over; Medicaid-eligible veterans;

former prisoners of war; veterans exposed to dioxin and other defoliants, such as Agent Orange, during the Vietnam War; and veterans exposed to nuclear testing or who served in Hiroshima or Nagasaki, Japan, between September 11, 1945, and July 1, 1946. Priorities must be established in providing for these groups because VA medical expenditures are limited. Veterans with service-connected disabilities are accorded top priority for medical and rehabilitative care, but approximately 80 percent of VA patients have non-service-connected disabilities.

Health benefits are administered by the VA Department of Medicine and Surgery, whose responsibilities include patient care, research, and education. Acute care for eligible veterans with medical, surgical, and psychiatric problems is provided in the VA medical centers, most of which are affiliated with medical schools. The VA pays for some care in non-VA hospitals, but usually only for veterans with service-connected disabilities. It provides ambulatory care in its outpatient clinics, although it also pays for some private physician visits on a fee-for-service basis. The VA has an extensive long-term care system, including nursing homes, domiciliaries, State veterans' homes, hospital-based home care, geriatric day care, hospice care, and community nursing home care.

A number of veterans' service organizations participate in the VA's delivery of health care. The largest of these organizations are The American Legion, the Veterans of Foreign Wars, and the Disabled American Veterans. Nationally, these groups attempt to influence legislation. Locally, they support community programs and often have an important influence on VA hospitals. Administrators respond to their inquiries and complaints and usually try to consult these organizations during major planning. Several veterans' service organizations have representatives on national advisory bodies to the VA and can influence national VA health care policy.

## Research and Development

The Federal Government's role in the research and development of devices, especially in prosthetic and disability-related research, dates back to the 1930s and 1940s. The VA and the Department of Defense conducted much of the initial research on prosthetic devices. Since 1947 the VA has spent over $30 million on prosthetic device research alone, while its other research and development has also grown.

Research and development falls under three Services: Medical Research, Health Services Research and Development, and Rehabilitation Research and Development (Rehabilitation R&D). Rehabilitation R&D affects the medical devices industry most directly, although the Medical Research Service uses major medical equipment and also clinically evaluates and monitors such devices as cardiac pacemakers. Rehabilitation R&D concentrates on prototype devices in three general areas: prosthetics and amputation (especially lower limb), spinal cord injury (in developing wheelchairs), and sensory aids (especially for the visually impaired).

Increased funding for Rehabilitation R&D may be warranted, especially for the full development of devices, since in the past some potentially worthwhile prototypes seem to have been abandoned in early stages. This problem results in part from the VA's lack of structured programs to disseminate information on research and development. The VA is now addressing this problem of technology transfer through its Office of Technology Transfer and an agreement with the Department of Commerce to disseminate information on promising technologies. VA procurement procedures have also presented a problem for VA research: long delays in obtaining needed research equipment.

## Testing and Evaluation

Once devices are commercially available, the VA may adopt them for use in its facilities or by veteran beneficiaries only after appropriate VA testing and evaluation. The Prosthetics and Sensory Aids Service evaluates rehabilitative devices, and the Office of Procurement and Supply tests and evaluates other types of medical equipment, such as X-ray equipment.

The VA has been active in standards development and has provided information on its work in this area to other public and private health care delivery groups. Throughout the 1970s, the VA increasingly used standards in its prosthetics and sensory aids programs. Not only were devices evaluated, but they were also tested for compliance with set standards. Concern grew about using the standards developed for existing technologies to evaluate and purchase new rehabilitative devices. Newer standards, therefore, have emphasized performance requirements. This policy has attempted to allow innovation and yet to provide adequate control for patient safety and welfare; its success is not yet clear.

The Testing and Evaluation Staff of the VA Marketing Center in Hines, Illinois, tests and evaluates medical devices and systems purchased by the VA. The staff is part of the Office of Procurement and Supply, not part of the Department of Medicine and Surgery (fig. 2). Medical devices are selected for evaluation through requests by VA medical centers, manufacturers, or the VA Central Office, as well as through the Testing and Evaluation Staff itself. Factors affecting selection include potential volume and interest on the part of the VA. Tests are usually consumer research tests, although sometimes other types of tests are conducted in cooperation with the Medical Research Service, the Department of Defense, or outside private testing laboratories. Evaluations are advisory and do not obligate VA medical centers to purchase particular products.

Both methodological and organizational problems have been identified in VA testing and evaluation. The VA's several testing and evaluation units may duplicate efforts. In addition, the units lack control in carrying out experimental protocols. New organizational plans may ameliorate these problems if they are implemented. Comparative evaluations could be good additional sources of information for procurement decisionmaking.

## Marketing, Procuring, and Supplying Devices

The Marketing Research and Analysis Program at the VA Marketing Center is a procurement resource that gathers and analyzes information on the range and quality of commercially available products and their compatibility with VA needs.

The size of the VA market allows it to buy medical supplies economically through centralized procurement. VA centralized procurement for its medical centers and for other Government agencies encompasses several programs. There is evidence that centralized VA procurement of some medical devices, such as catheters, needles, syringes, surgical blades, and pacemakers, has enabled the VA to obtain lower prices than other public and private organizations. VA policies on procurement have also affected the prices of several types of major medical equipment (as shown by the study presented in app. C).

Under the terms of the most favored customer clause in VA procurement contracts, suppliers are not allowed to sell their products under similar contracts to any private buyer at a price lower than that offered the VA. This policy has reduced VA procurement costs, although it may also have increased costs to private buyers.

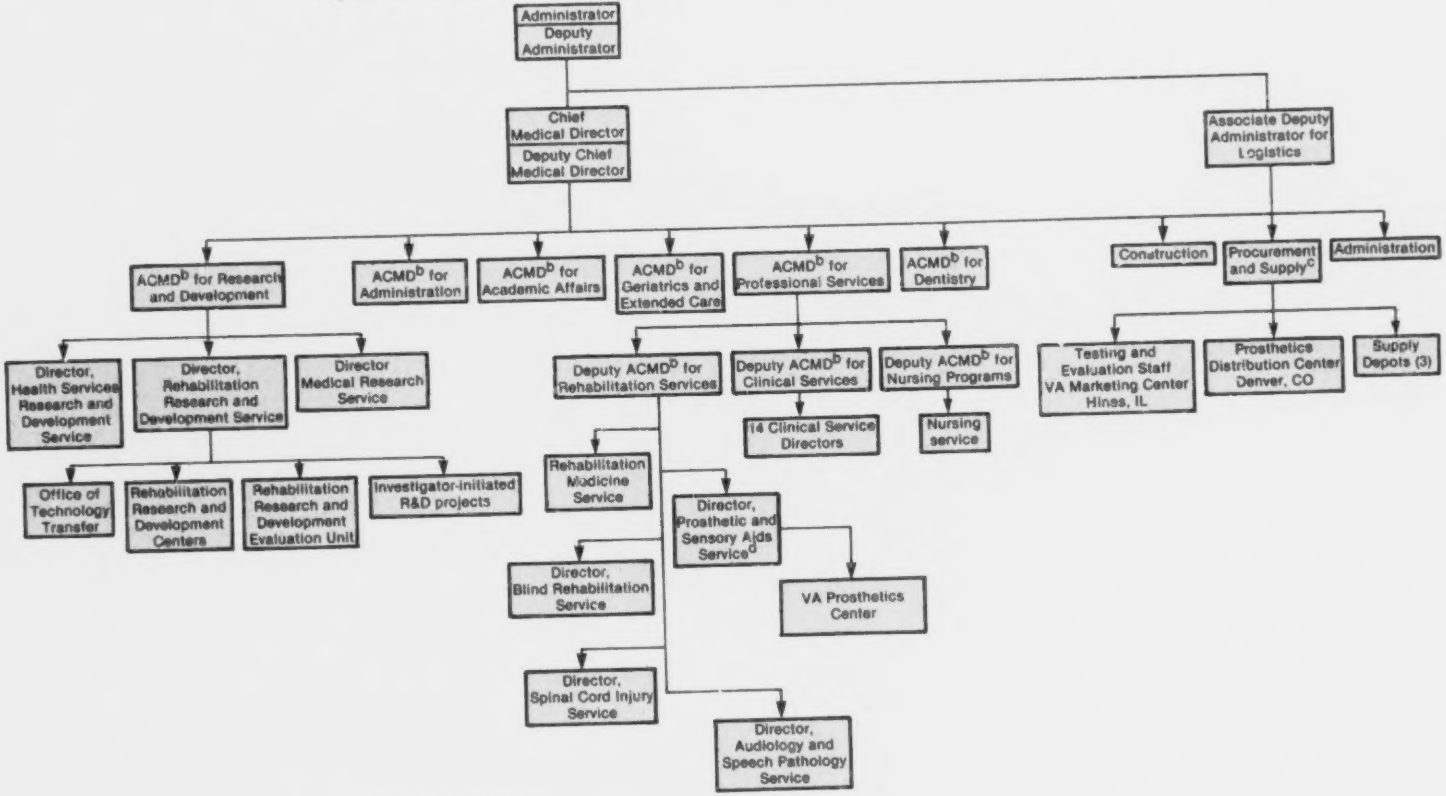
Because of the VA's brand name justification requirement, VA hospitals must justify purchasing equipment from other than the least-cost supplier on the VA list (e.g., based on service availability). Suppliers are anxious to maintain their share of the VA market, and it is likely that they lower prices to be competitive given this requirement.

VA contracts with suppliers state that prices may not be increased during the contract year, and if they decrease prices, the lower price holds for the remainder of the year. This firm fixed price clause protects the VA from price increases during a year, but suppliers may charge a higher initial price than they would in the absence of the clause.

By law, the public has access to information on VA Marketing Center procurement prices for medical equipment. This public disclosure requirement may result in higher procurement costs for two reasons. It reduces the so-called retaliation lag (the time before rival companies learn of price cuts and reduce their own prices in response). Also, the publicly known VA price may become private buyers' target price.

The VA Marketing Center does not make volume commitments, which may result in raising VA prices for many kinds of equipment. This re-

Figure 2.—Organization Chart of the Veterans Administration (VA),[a] May 1984


Administrator
Deputy Administrator
Chief Medical Director
Deputy Chief Medical Director
Associate Deputy Administrator for Logistics
ACMD^b for Research and Development
ACMD^b for Administration
ACMD^b for Academic Affairs
ACMD^b for Geriatrics and Extended Care
ACMD^b for Professional Services
ACMD^b for Dentistry
Construction
Procurement and Supply^c
Administration
Director, Health Services Research and Development Service
Director, Rehabilitation Research and Development Service
Director Medical Research Service
Deputy ACMD^b for Rehabilitation Services
Deputy ACMD^b for Clinical Services
Deputy ACMD^b for Nursing Programs
Testing and Evaluation Staff VA Marketing Center Hines, IL
Prosthetics Distribution Center Denver, CO
Supply Depots (3)
14 Clinical Service Directors
Nursing service
Office of Technology Transfer
Rehabilitation Research and Development Centers
Rehabilitation Research and Development Evaluation Unit
Investigator-initiated R&D projects
Rehabilitation Medicine Service
Director, Prosthetic and Sensory Aids Service^d
VA Prosthetics Center
Director, Blind Rehabilitation Service
Director, Spinal Cord Injury Service
Director, Audiology and Speech Pathology Service

[a] This chart shows the relationships among the parts of the VA discussed in this chapter.

[b] ACMD = Assistant Chief Medical Director.

[c] VA supply services are located in individual VA medical centers.

[d] The Prosthetic Technology Evaluation Committee advises the Prosthetics and Sensory Aids Service.

SOURCE: Office of Technology Assessment.

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sult depends in some measure on whether the equipment is expensive or inexpensive because of the relative transaction costs of contracts, where significant savings may be realized. An unofficial VA policy is to avoid procuring mixed equipment systems (components from several manufacturers combined in systems), to reduce warranty problems. This policy may increase procurement costs, but it may decrease repair costs.

The VA Marketing Center has also encountered problems in attempting to ensure product quality, largely because of its increasing use of simplified purchase descriptions in place of more detailed product specifications and standards, which are being phased out in response to a 1980 Federal policy directive. Product quality is likely to improve when the VA better integrates all its information-gathering activities (research, development, testing, evaluation, marketing, etc.) into purchasing contract decisions.

Local supply officers are charged with procurement for the VA medical centers. The open market may be used to purchase items not available from centrally managed sources, needed for an emergency, or available at lower prices than through the central Federal Supply Schedule program managed by the VA. In the early 1960s, open market procurement (i.e., purchases made directly by individual VA medical centers) accounted for about 10 percent of purchases; the figure is now about 39 percent. More open market purchasing permits hospital staff to select manufacturers and models that they prefer and, perhaps, to receive orders more quickly. Nevertheless, such individual purchases prevent the VA from using its potential buying power to gain lower prices through volume purchases.

## Adopting, Using, and Financing Devices

All VA activities relating to medical devices have the goal of the adoption and use of good-quality, low-cost medical technologies. Because of social and political incentives to overadopt some medical devices and because of financial constraints on others, the VA has sporadically adopted devices and other technologies, and its distribution of resources may not be equitable or efficient across geographic areas and facilities. More comparative analyses of medical devices and equipment are needed to ensure better results in this regard.

The issue of financing medical devices has increased in importance as the population of veterans ages and more of them need the assistance such devices provide. The high costs of providing unlimited prostheses to veterans, as law requires, and the use of high technology in health care draw funds from the rest of the VA health care activities.

Decisions about adopting and using new medical devices would ideally be based on information about veterans' needs and the safety, efficacy, and costs of the devices and their alternatives. However, not all needed data are always available, and current VA decisionmaking does not necessarily consider all the available data. The VA lacks formal processes to decide which VA medical centers should adopt new, expensive devices and to allocate funds among the medical centers for such purchases.

Because of limited resources, in fiscal year 1981 the VA adopted a system of strategic planning, Medical District Initiated Program Planning. As new device and equipment requests are made through medical district plans, the evaluation of technologies could be focused and the adoption of new technologies could be based on more accurate information.

## Conclusions

The VA's current system of medical device-related research, development, evaluation, procurement, and use has a number of significant weaknesses. Better analytical methods for evaluating and procuring the most appropriate devices at least cost could be applied at various points in technology development and use.

VA research and development, evaluation, and procurement have often been poorly integrated. The VA's potential market leverage in procuring devices, for example, has not been realized in stimulating the development of certain devices. Nor have the results of the VA's own research, development, and evaluation been systematically incorporated in the VA's procurement and adoption decisions.

The VA recently initiated several new programs and committees that may greatly improve the VA's development and use of medical devices. The Rehabilitation R&D Service's new Evaluation Unit, which will coordinate and improve the testing of prototype rehabilitative devices, and the Prosthetic Technology Evaluation Committee, which will develop a formal evaluation and coordination process for commercially available products, are two notable efforts. These improvements in evaluation processes may result in more appropriate adoption and use of medical devices and other technologies by the VA, and indirectly, by other Government agencies and the private sector.

A last important sign of the VA's new directions is the recent formation of a High Technology Assessment Group to determine future VA policy on acquiring major new technologies. The High Technology Assessment Group could help develop information for allocating health care resources more efficiently and equitably than in the past.

## ORGANIZATION OF THIS TECHNICAL MEMORANDUM

This memorandum groups medical devices into three general classes: *rehabilitative devices* (orthotic and prosthetic devices, such as artificial limbs), *equipment* (radiological and laboratory devices), and *supplies* (bandages, disposables, etc.). It should be noted, however, that the diversity of medical devices defies easy classification. Medical devices include products used for different medical purposes (preventive, diagnostic, therapeutic, and rehabilitative) and by different branches of medical care (e.g., dentistry, ophthalmology, orthopedics, and neurology).

Chapter 2 provides the context for discussing present VA policies on medical devices and describes briefly the history and characteristics of the VA health care delivery system. Chapters 3 through 6 address the VA's involvement in research and development; testing and evaluation; marketing, procurement, and supply; and financing, adopting, and using devices.

Appendix A acknowledges the valuable assistance of the Health Program Advisory Committee and other individuals for their information, advice, and review of drafts. Appendix B reviews veterans' service organizations and their perspectives on the VA health care delivery system. Appendix C examines VA procurement of eight types of medical equipment and the effects of VA purchasing policies on private manufacturers and buyers of such medical equipment.

## Chapter 2

# The Veterans Administration and Health Care: An Overview

## Chapter 2

# The Veterans Administration and Health Care: An Overview

The Veterans Administration (VA) provides a broad range of services for veterans and their dependents. These benefits include compensation payments for service-related disability or death, pensions based on financial need for totally disabled veterans and certain survivors of veterans for non-service-related disability or death, education and rehabilitation, home loan guarantees, burial, and—most importantly for this study—free or subsidized hospital, ambulatory, and extended medical care, including nursing home care, to eligible veterans.

VA health care is administered by its Department of Medicine and Surgery (DM&S), which had a budget of $8.1 billion in fiscal year 1983.[1] Title 38 of the U.S. Code (sec. 4101) provides that the functions of DM&S ". . . shall be those necessary for a complete medical and hospital service, including medical research . . . [and] to carry out a program of training and education of health service personnel, acting in cooperation with schools. . . ." Thus, DM&S has a three-part mission of patient care, research, and education (150). DM&S is administered from the Central Office in Washington, DC, and is headed by a Chief Medical Director. Specific areas of patient care and program function, such as rehabilitation medicine, surgery, radiology, and medical research, are termed "Services" and are under the Central Office guidance of Service Directors. An organizational chart is shown in figure 3.

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[1] The budget was $6.96 billion in fiscal year 1981 and $7.59 billion in fiscal year 1982. These figures include construction, research, and administrative costs, which together account for less than 10 percent of all hospital and medical care expenditures (97).

## HISTORICAL PERSPECTIVE[2]

Federal programs for veterans date to the Revolutionary War. Until early in this century, however, they were almost exclusively pension programs; what medical and hospital care was available was provided by States or communities.

The VA medical program evolved through a series of legislative enactments during and after World War I. The war added nearly 5 million people to the Nation's veteran population, and new programs were required to meet their many needs. In 1921 Congress created the U.S. Veterans Bureau, which consolidated the functions of several agencies that had been administering veterans' programs. The veterans' hospital system was created in 1922 when 57 Public Health Service hospitals were transferred to the Veterans Bureau. The system was constructed rapidly for the many World War I veterans with service-connected injuries. Within a few years, however, the number of service-connected cases were no longer sufficient to fill available bed space. As a result, in 1924 Congress passed legislation expanding eligibility for hospitalization benefits to encompass indigent veterans with non-service-connected health needs.

This pattern was repeated after World War II: after the immediate needs of the war's veterans were met, the system again had excess capacity and the process of expanding the scope of medical benefits continued. In recent years most VA hospital patients have been treated for problems unrelated to military service. Over the years the

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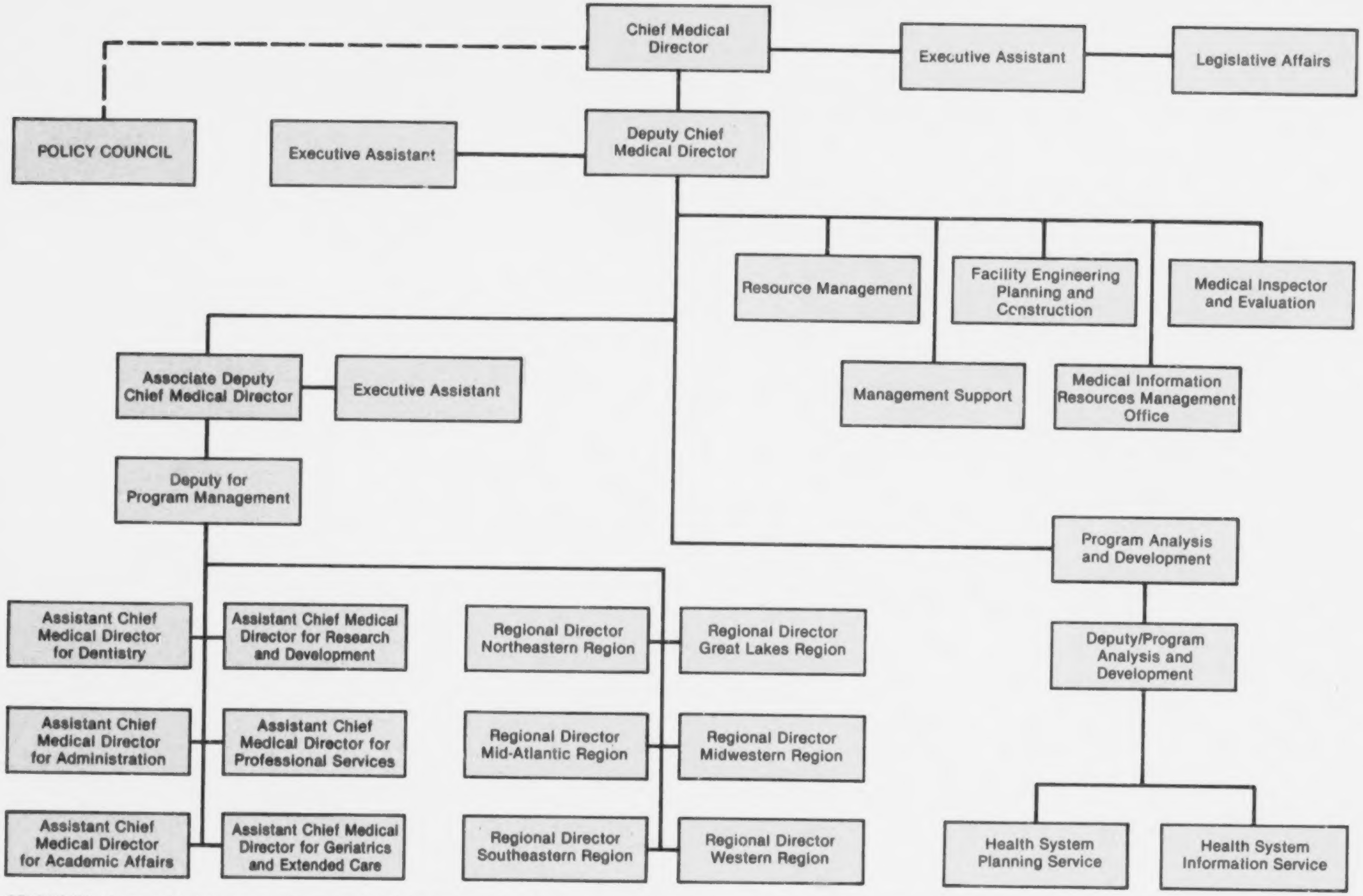
[2] Except where noted, this section is adapted from U.S. Congress, Congressional Research Service, *Medical Care Programs of the Veterans Administration* (Report No. 83-99 EPW, Washington, DC, May 16, 1983).

Figure 3.—VA Department of Medicine and Surgery


Chief Medical Director
Executive Assistant
Legislative Affairs
POLICY COUNCIL
Executive Assistant
Deputy Chief Medical Director
Resource Management
Facility Engineering Planning and Construction
Medical Inspector and Evaluation
Management Support
Medical Information Resources Management Office
Associate Deputy Chief Medical Director
Executive Assistant
Deputy for Program Management
Program Analysis and Development
Deputy/Program Analysis and Development
Assistant Chief Medical Director for Dentistry
Assistant Chief Medical Director for Research and Development
Regional Director Northeastern Region
Regional Director Great Lakes Region
Assistant Chief Medical Director for Administration
Assistant Chief Medical Director for Professional Services
Regional Director Mid-Atlantic Region
Regional Director Midwestern Region
Assistant Chief Medical Director for Academic Affairs
Assistant Chief Medical Director for Geriatrics and Extended Care
Regional Director Southeastern Region
Regional Director Western Region
Health System Planning Service
Health System Information Service

SOURCE: U.S. Veterans Administration, Department of Medicine and Surgery, Office of the Chief Medical Director, Washington, DC, Oct. 1, 1982.

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VA's medical role has grown in four general directions:

- providing more health care to veterans with non-service-connected disabilities,
- providing a greater range of health care services,
- training health care personnel and conducting medical research, and
- providing some services to certain nonveterans.

Another major development in VA medical care after World War II was the affiliation of VA hospitals with medical schools. In the 1920s and 1930s the VA hospital system had become somewhat isolated from the professional medical community. VA affiliation with medical schools was viewed as a way to overcome this isolation and improve the quality of care for veterans. Public Law 79-293, which established DM&S within the VA, authorized the affiliation program. On balance, these affiliations appear to have been beneficial to all concerned. The Nation's veterans have had better care, and the Nation's doctors have been better educated (62).

The VA now provides most of its health care services in VA hospitals, domiciliaries, nursing homes, and outpatient clinics. In addition, under current law, the VA may contract for medical care in government or community facilities, but only if care either cannot be provided or cannot be more economically provided in VA facilities. In 1981 the VA contracted for nursing home care in 2,900 community nursing homes and subsidized care on a limited per diem basis at 44 State veterans' homes, including hospitals, nursing homes, and domiciliaries. Noninstitutional care is also provided for veterans through hospital-based home care programs, geriatric day care centers, and residential care programs.

## VA HEALTH CARE SERVICES[3]

### Acute Care Services

Acute care services are provided mainly in VA hospitals, or medical centers, which are the primary source of medical care for veterans. In fiscal year 1981 about 1.25 million patients were treated in VA hospitals, 1.22 million in medical and surgical beds and 206,000 in psychiatric bed sections; only about 30,400 were treated in non-VA hospitals at VA expense. VA hospital care includes skilled medical and surgical procedures and intensive diagnostic and therapeutic services (fig. 4). The quality of VA hospital care is generally thought to be enhanced by the affiliations of most VA medical centers with medical, nursing, or dental schools.

The number of VA acute care beds has declined over the last several years. The VA operated an average of 82,079 hospital beds during 1981, compared to more than 97,000 beds during 1973. Many changes in the VA system have led to the decline in total hospital beds, notably a decline in the number of psychiatric hospital beds. Medical and surgical beds have also been closed because of shorter lengths of stay and shifting patients to outpatient care. Recent legislation requires the VA to operate at least 90,000 total hospital and nursing home beds (Public Law 97-72) and to have sufficient beds in readiness to support the Department of Defense in times of declared war (Public Law 97-174).

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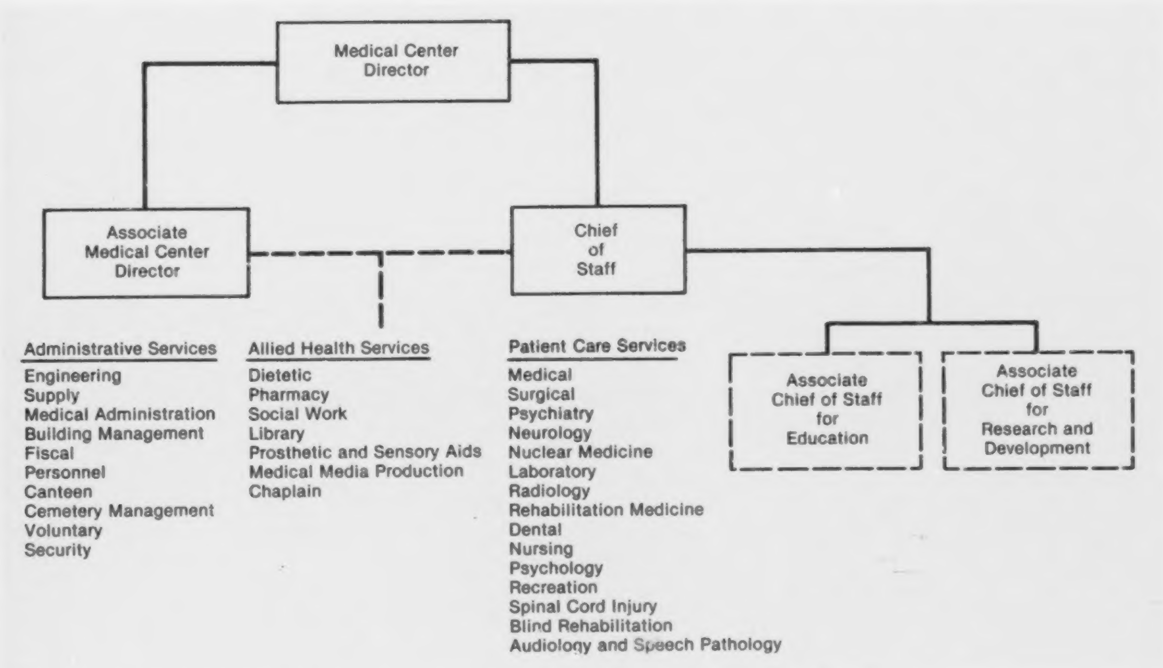
[3] This section is adapted from U.S. Congress, Congressional Budget Office, *Veterans Administration Health Care: Planning for 1990* (Washington, DC, February 1983).

Figure 4.—Medical Center Hospital


Medical Center Director
Associate Medical Center Director
Chief of Staff
Associate Chief of Staff for Education
Associate Chief of Staff for Research and Development
Administrative Services
Engineering
Supply
Medical Administration
Building Management
Fiscal
Personnel
Canteen
Cemetery Management
Voluntary
Security
Allied Health Services
Dietetic
Pharmacy
Social Work
Library
Prosthetic and Sensory Aids
Medical Media Production
Chaplain
Patient Care Services
Medical
Surgical
Psychiatry
Neurology
Nuclear Medicine
Laboratory
Radiology
Rehabilitation Medicine
Dental
Nursing
Psychology
Recreation
Spinal Cord Injury
Blind Rehabilitation
Audiology and Speech Pathology

SOURCE: U.S. Veterans Administration, VA Organization Manual M-00-1, Change 11, p. X-74 (Washington, DC, July 30, 1981)

## Long-Term Care Services

The VA provides both institutional and noninstitutional long-term care services. Institutional services include those of the 101 nursing home units associated with VA medical centers and those provided in community nursing homes, State veterans' homes, and domiciliaries. Noninstitutional care consists of monitoring the health of patients in their own homes, in congregate (group) homes, and at day care centers. Special programs begun in recent years support noninstitutional care, such as hospital-based home care and geriatric day care.

### VA Nursing Home Care

The VA nursing home units provide the most highly skilled and most intensive extended care after hospitalization, with no time limits. In 1981 the VA operated an average of 8,700 nursing home beds. Most VA nursing homes are almost filled: in fiscal year 1982, 54 of 98 VA nursing homes had occupancy rates above 95 percent.

### Community Nursing Homes

The VA also contracts per diem for skilled nursing care at regularly inspected community nursing homes. Over 28,200 veterans were cared for in these homes in 1981. According to the VA, veterans are usually placed in such homes when they do not require the level of care provided in VA nursing homes.

### State Veterans' Homes

State veterans' homes are facilities established by the State for medical and residential care of veterans. Two VA grant programs support State

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veterans' homes. A per diem program helps the State provide hospital, nursing home, and domiciliary care to veterans. Another VA program contributes to State construction of new domiciliary and nursing home facilities and expansion and remodeling of existing facilities. The VA subsidized care in State homes for over 24,700 veterans in 1981.

### VA Domiciliaries

Domiciliaries, the forerunners of the VA programs, date from legislation in 1866 that established Soldiers' Homes for disabled veterans. VA domiciliaries are usually located in the complex of VA medical centers. Veterans placed in domiciliaries must be service-disabled or permanently disabled and unable to support themselves. Their health often requires some monitoring although not so much as is provided in skilled nursing homes. In 1981 the VA provided domiciliary care for over 14,800 persons.

### Hospital-Based Home Care

The VA helps patients with residual disabilities to remain in their own homes. Patients and their families are given appropriate instructions in routine nursing procedures, supervised by a hospital-based treatment team. The team includes a physician, public health nurse, social worker, rehabilitation therapist, and other specialists. Frequency of home visits depends on the patient's needs and treatment plan. In 1981 teams at 30 hospitals served 5,600 patients, one-fifth of them terminal cancer patients.

### Geriatric Day Care

Although several related VA programs are in operation, the day care program is a new VA project in which older veterans are helped to return to their own homes. Under day care programs, veterans continue in rehabilitation at community centers or outpatient clinics under VA auspices. Model programs are in operation at the Chicago and Boston medical centers and in a community near the Loma Linda, California, medical center in coordination with The American Legion.

## Ambulatory Care

The ambulatory care and outpatient clinical programs are vital in the VA health care system as an alternative to hospitalization. The VA operates mental hygiene clinics and day treatment centers for psychiatric patients. Clinic services are also used for care prior to and after hospitalization. Outpatient clinics also help control chronic conditions, such as arthritis, hypertension, and diabetes, that are often associated with aging. In 1981 more than 15.8 million outpatient medical visits were made to VA staff and 2.1 million visits were made to private physicians funded on a fee-for-service basis by the VA.

## Other Services

The VA also operates other outpatient programs to supplement its main hospital and nursing home services. For example, dental care is given to eligible veterans and the VA considers it a necessary service for the total care of patients in acute care or long-term care facilities.

In addition, the VA established Geriatric Research, Education, and Clinical Centers (GRECCs) for the growing number of elderly veterans. There are currently eight such centers, although 15 are authorized by legislation (Public Law 96-330). GRECCs are located at VA medical centers and use the research and clinical activities of affiliated medical schools. One goal of the program is to train new geriatric practitioners, teachers, and researchers.

The growing aged veteran population is a major concern of the VA. By 1990 practically all World War II veterans, now 12 million persons, will be 65 or older. Although most will be eligible for free VA health care, only about 2 million are expected to apply for such health care, including 400,000 service-disabled veterans. The VA proposes to construct additional nursing home beds and should have more than 13,000 after 1987. If this number is insufficient, the VA may rely on alternative sources such as community or State nursing homes.

## THE VETERAN PATIENT POPULATION[4]

The VA provides health benefits only to the eligible population. Those eligible are primarily veterans with service-connected disabilities, those discharged from active service because of illness or injury incurred or aggravated in the line of duty, former prisoners of war, those exposed to Agent Orange in Vietnam, veterans 65 or older, and veterans unable to pay for their medical care. (Eligibility for VA health care is discussed further in ch. 6.) Although seldom required, VA facilities can also provide medical care to members of the Armed Forces, dependents or survivors of service-disabled veterans, and other nonveterans for humane reasons or emergency care.

There are approximately 30 million veterans, of whom 98 percent are male. Forty percent are World War II veterans, now in their 50s and 60s. Only a small number of all veterans however, are currently served by the VA health care system. About 3 million veterans—10 percent of the veteran population—used VA services during 1981. Most veterans use community facilities and services for medical care, presumably because these veterans have sufficient public or private health insurance or prefer the proximity of non-VA facilities. Veterans receiving VA care have health insurance less frequently than those receiving non-VA care.

Most VA services are provided to veterans with service-connected disabilities or to low-income veterans without insurance. In fiscal year 1982, 34 percent of the applicants for VA medical care were service-disabled veterans; such veterans apply for care six times more frequently than other veterans. Service-disabled veterans are more likely to need greater medical care, particularly the specialized care offered by the VA, and have priority by law.

A significant part of VA health care is given to and requested by the aged. Aged veterans apply for VA care twice as often as younger veterans, accounting for almost 20 percent of applications. In 1981, 17 percent of veterans aged 65 or older applied for medical care at VA facilities, compared to only 8.5 percent of veterans under 65. In the same year, the VA funded medical or health benefits for over 798,000 veterans 65 or older; one-fourth of patients discharged from VA hospitals —about 236,800—were 65 or older.

## VETERANS' SERVICE ORGANIZATIONS[5]

Veterans' service organizations play a significant role in the VA's delivery of health care, including medical devices. The major organizations —The American Legion, the Veterans of Foreign

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[4] This section is adapted from U.S. Congress, Congressional Budget Office, *Veterans Administration Health Care: Planning for 1990* (Washington, DC, February 1983).

[5] This section is adapted from S. C. Farrow, A. D. Kaluzny, and T. Ricketts, "Proceedings of a Conference on Health Services Research Issues in the Veterans Administration," *J. Medical Systems* 5(1/2):1-16, 1981. For further information on veterans' service organizations, see app. B.

Wars, and the Disabled American Veterans—are all powerful influences both locally, where they are involved in a variety of activities, such as community programs for youth, and nationally, where they serve their members in the political arena. Some organizations represent specific disabilities, some particular conflicts, and others ethnic and religious affiliations. Thus their interest groups sometimes overlap.

Through their local chapters, these organizations significantly influence VA hospitals. The groups provide hours of volunteer work offering support and advice to patients and their families. Occasionally, they strongly pressure a hospital director to support a particular policy. Local hospitals are sensitive to such pressure and respond to inquiries and complaints. Although veterans' service organizations are not always involved in planning, they are consulted at times, particularly about reducing services or changing bed designations.

Nationally, these organizations attempt to affect legislation, notably proposals to reduce services, although occasionally they lobby for new services, such as drug treatment centers for Vietnam-era veterans.

The opinions of veterans and veterans' organizations about the VA and medical devices are examined throughout this study and in detail in appendix B. This chapter has provided a brief overview of the VA's health care system and the population it serves. The next four chapters examine VA programs and activities bearing most directly on the development and use of medical devices.

## Chapter 3

# Research and Development of Devices

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# Research and Development of Devices

Though the Federal Government purchased medical devices as long ago as the years following the Civil War, groundwork for the current system of device-related research and development was laid in the 1940s by the National Academy of Sciences and the Armed Forces in response to the postwar needs of veterans. Much initial research on prosthetic devices was conducted by the Department of Defense (DOD) and the Veterans Administration (VA). Since 1947 the VA has spent over $30 million on prosthetics research alone. Prosthetics research, along with growing research in other areas, still continues in the VA system (109).

VA research and development are now divided among three programs or "services": Medical Research, Health Services Research and Development, and Rehabilitation Research and Development (Rehabilitation R&D). Only the last, Rehabilitation R&D, is substantially concerned with medical devices and so is the main focus of this chapter. The other two services are briefly described, since their programs do affect device evaluation and procurement specifically and technology transfer generally, as later chapters report.

## MEDICAL RESEARCH

The Medical Research Service provides opportunities for clinicians and scientists to study the health problems of veterans. During fiscal year 1981 approximately 4,100 investigators participated in 5,440 medical research projects conducted at 129 VA health care facilities, including medical centers and independent outpatient clinics (118). Since many VA investigators are health care providers in VA medical centers, many of these studies emphasize the practical care of veterans and the general population (119).

### Research Programs

The *Merit Review Program* is by far the largest program within the Medical Research Service, involving approximately 2,000 funded investigators. This research is investigator initiated, as opposed to centrally directed. Although the program supports basic science, it emphasizes clinical research. Approximately 85 percent of all principal investigators in the VA system are physicians who carry out their research part time, spending most of their time with veteran patients. Research interests arise from daily clinical practice, and results are applied to patient care. Each investigator pursues his or her own interests, and each competes against all the others for funding.

*High Priority Research* focuses on problems of particular importance to veterans, whether because of the prevalence or incidence of a condition or because it results from military service, especially from combat (142). Current research areas are aging, spinal cord injury and tissue regeneration, schizophrenia, alcoholism, Agent Orange, and delayed stress disorders.

The *Cooperative Studies Program* supports multicenter clinical trials within the VA system. The program is administered through the VA Central Office in Washington, DC, and has one experimental drug unit and four centers to coordinate data in different parts of the country.

As of September 1982, 19 studies were in progress, 11 were in active planning, and 12 were in final analysis (106,142). The largest number of trials have tested drug therapies, followed by trials of types of surgery, such as coronary artery bypass grafts. Although most trials have concerned treatments, many have also focused on preventive health care measures, such as control of hypertension. The mix of VA clinical trials is much like that of the National Institutes of Health (NIH), except that fewer VA trials focus on cancer treatment.

Clinical trials follow a well-defined path from inception to publication. Ideas for studies come from VA physicians and investigators around the country. They are considered by VA panels and outside advisers, and if judged worthwhile and appropriate for VA research, are planned and carried out. Each study is assigned to a coordinating center for help in designing, conducting, and analyzing the trial (106).

The Cooperative Studies Program enables researchers to obtain large enough samples with geographic diversity to permit valid generalizations—for example, about the relative values of different treatments or the etiology and natural history of a medical disorder. One Army-VA Cooperative Study revolutionized the treatment of tuberculosis, virtually emptying tuberculosis wards in the early 1950s (142).

### Other Medical Research

The VA not only funds research, it is also involved in clinical trials funded by others, such as NIH and pharmaceutical companies (106). The Medical Research Service maintains a computerized data system that encompasses all VA research, including that funded by outside sources.

The VA also supports the retrospective collection and analysis of data on medical procedures and devices, which, although not intended for research can still be used in research. For example, a 1980 VA Inspector General Audit of cardiac pacemaker procurement concluded that the VA's requisition and monitoring of pacemakers should be more closely controlled (120). Senate hearings later that year raised concerns about the VA's ability to track pacemaker patients and to identify and protect those affected by recalls. These events prompted the VA to develop a pacemaker registry and prosthesis profiles for all VA pacemaker patients. The registry is now reviewed periodically for both procurement and clinical care, and information is exchanged with other interested Government agencies, such as the Food and Drug Administration, DOD, and NIH (113).

## HEALTH SERVICES RESEARCH AND DEVELOPMENT

The Health Services Research and Development Service (HSR&D) develops and supports projects to evaluate alternative policies and technologies for clinical and administrative decisionmaking in VA health care. HSR&D emphasizes management tools, as in developing an information system for VA clinicians, administrators, researchers, and consumers (31,119).

Recent broad research priorities focus on care of the aged veteran, VA health care operations, the cost effectiveness of patient care technologies, rehabilitation services, and preventive health care. HSR&D supported 36 investigator-initiated research projects at 25 VA medical centers during fiscal year 1982. In a VA pilot program of preventive health care established in response to Public Law 96-22, subjects of research are schizophrenia, hypertension, psychiatric screening, and dentistry, along with the evaluation of some preventive health care services (32,119).

Four regional field programs have recently been established to integrate research with the information requirements of managers and clinicians. These field programs conduct research, provide technical assistance to investigators and consultation to administrators and clinicians, educate VA staff about the uses of health services research, and serve as a systemwide resource in such areas as care of the aged veteran, ambulatory care, and operational efficiency. In addition, HSR&D addresses information needs of VA Central Office managers.

# REHABILITATION RESEARCH AND DEVELOPMENT

Rehabilitation R&D (formerly Rehabilitation Engineering R&D) is the most directly important VA Service in relation to medical devices. Rehabilitation R&D was the VA's response to the needs of disabled people, particularly veterans. The Service evolved from the R&D Division of the Prosthetic Service, dating back to 1946, and was at first mainly an artificial limbs program. In 1973, as a result of increased national focus on rehabilitation research and engineering needs, Rehabilitation R&D was separated from other VA R&D and given a mandate to improve the quality of life and facilitate the independence of physically disabled veterans (109,127). This mission is to be accomplished through research, development, and evaluation of new devices, techniques, and concepts in rehabilitation. The Rehabilitation Act of 1973 (Public Law 93-112), additionally requires Rehabilitation R&D to cooperate and coordinate activities with the National Institute of Handicapped Research. Legislation further requires research and development for automotive adaptive equipment (153).

Rehabilitation R&D primarily develops sophisticated, "usable" devices to help individuals. Other goals include improved rehabilitation methods (e.g., functional electrical stimulation and methods to avoid decubitis ulcers, or bedsores) and technology transfer, including increasing the availability of new devices on the open market. Rehabilitation R&D does not directly furnish or fabricate devices for veterans; rather, prototype devices are developed and adapted from commercially available items purchased from local private sources (153). Successful models may then be produced commercially.

Rehabilitation R&D organizes both intramural and extramural research and development programs, has established Rehabilitation R&D Centers and research affiliations with engineering schools, and generally attempts to ensure the dissemination and clinical use of new devices, techniques, and concepts (144).

The topics of Rehabilitation R&D range from traditional artificial limbs to robotic devices for the totally paralyzed person (153). Activities are concentrated in three areas, representing the most prevalent service-connected disabilities:

- *Prosthetics and amputation*. Rehabilitation R&D emphasizes lower limb prosthetics, including improved fitting techniques, especially for the elderly. Rehabilitation R&D is now most heavily committed to this area, which represents about 40 percent of its total budget.
- *Spinal cord injury*. Rehabilitation R&D devotes about 30 percent of its budget to improving wheelchairs by improving motor and controller efficiency, reducing noise, and developing a fail-safe braking system.
- *Sensory aids*. Special emphasis is given to aids for visually impaired people. Studies include those of new sensory aids, people's mobility and orientation needs, and new communication and vocational aids. This area represents about 30 percent of the Rehabilitation R&D budget (119,152).

Table 1 presents a summary list of Rehabilitation R&D projects in fiscal year 1983. Research priorities are identified in special meetings, which include representatives from rehabilitation research, clinicians, manufacturers, and disabled veterans' consumer groups. Workshops and seminars in fiscal year 1982 focused on hearing impairment, prosthetics, and commercializing VA technology (152). (For the views of veterans' groups on VA research, see app. B.) Rehabilitation R&D has not traditionally supported device development for cardiovascular, pulmonary, and renal disabilities because they have seldom been service connected (153). However, such devices may receive attention in the Medical Research Service and be used in VA clinical practice.

## Rehabilitation R&D Centers

Three VA Centers perform and support rehabilitation research and development. The VA Prosthetics Center (VAPC) in New York City[1] is

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[1] Within the VA, VAPC has also unofficially been known as the Prosthetics Evaluation, Testing, and Information Center, and the Rehabilitation Engineering Center.

**Table 1.—Summary of Rehabilitation Research and Development Projects, Fiscal Year 1983**

| Topic | Number of projects |
|---|---|
| ***Prosthetics/amputation:*** | |
| Diagnostic procedures | 4 |
| Surgical procedures | 9 |
| Internal joint/prostheses | 17 |
| Gait analysis | 5 |
| Maxillofacial prostheses | 1 |
| Prosthetics and orthotics | 8 |
| Total | 44 |
| ***Spinal cord injury:*** | |
| Mobility (including wheelchairs and automotive adaptive equipment) | 6 |
| Manipulative devices (including computer-assisted devices and environmental controls) | 2 |
| Surgical procedures | 5 |
| Neuromuscular control (including functional electrical stimulation, nerve conduction studies, and neural models) | 10 |
| Total | 23 |
| ***Sensory aids:*** | |
| Blindness and visual impairment | 8 |
| Deafness and hearing treatment | 9 |
| Speech impairment | 5 |
| Total | 22 |
| ***Technology dissemination and use:*** | |
| Rehab R&D centers | 2 |
| Rehab R&D affiliation | 2 |
| Information dissemination | 6 |
| Total | 10 |

SOURCE: Office of Technology Assessment, 1984.

organizationally separate from Rehabilitation R&D.[2] VAPC was established in 1956 to conduct research and development in rehabilitation engineering, to evaluate commercially available devices, to provide customized devices for difficult cases,[3] and to manufacture and distribute orthopedic footwear and prosthetic and orthotic devices. In the 1950s, VAPC was the basis of a successful VA intramural research program, developing most of the prosthetic limbs and the fitting techniques used today (127).

A recent audit report (1982) by the VA's Office of Inspector General, however, disclosed substantial management problems at VAPC over the last several years and recommended changes in its goals and organization, including the discontinuation of its research and development program (139). The VA hopes to transfer VAPC's Development Section to the Technology and Performance Evaluation Service. Personnel in the Research Section were offered reassignment to the Engineering Service at a nearby VA hospital (22). (Other VAPC activities and program changes are discussed later in this report.)

The other two Rehabilitation R&D Centers were established only in the last few years and are directly tied to the VA Rehabilitation R&D program. One is in the Palo Alto VA medical center in California, the other in the Hines, Illinois, VA medical center outside Chicago. Six more Centers are planned by 1986.

These Centers provide engineering support in VA medical centers where there are existing relationships between VA medical and engineering communities, and they are affiliated with leading engineering schools, just as VA medical centers are affiliated with medical schools. These affiliations bring faculty and students into clinical research settings to study the problems of disabled people and new procedures and devices in engineering. The Centers' primary goal is to apply advanced technology (e.g., microprocessors) to help physically handicapped veterans. The VA views the Centers as natural outcomes of engineering school affiliations that successfully produced new rehabilitative devices, techniques, and concepts in VA clinical settings.

Each Rehabilitation R&D Center is administered by a director and an assistant director, one a physician and the other a rehabilitative engineer. Each Center is staffed with investigators and technicians, but receives administrative support from its associated health care facility (144).

The Rehabilitation R&D program is also establishing university-affiliated engineering research programs to help support graduate students and faculty who undertake rehabilitation engineering projects. The program is designed not only to interest engineering students in rehabilitation, given the critical shortage of trained rehabilitation engineering professionals in this country, but also to infuse new ideas into the Rehabilitation R&D program through its frequent communication with academia (19,30,109).

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[2] Since this technical memorandum was drafted, the VA has proposed a reorganization that would put VAPC, Rehabilitation R&D, and Prosthetics and Sensory Aids Service under one director.

[3] VAPC represents a merger of the New York Regional Office and the Prosthetic Testing and Development Laboratory, then part of the Research and Development Division of the Prosthetic and Sensory Aids Service, to bring research and clinical programs together for the benefit of each. In 1969, VAPC established a program of satellite stations to help its engineers and professional personnel work more closely with patients at the site of hospitalization. Such stations have been established at VA hospitals in Brooklyn, NY, East Orange, NJ, the Bronx, NY, and Castle Point, NY.

### Technology Transfer

Part of the VA's rehabilitation research program mandate (38 U.S.C. sec. 4101(c)(2)) is to test prosthetic, orthotic, and orthopedic appliances and sensory aids, and to disseminate VA results and information for the benefit of all disabled persons (154).

The VA has traditionally attempted to ensure the clinical use of new devices, techniques, and concepts in three major ways:

- Through VA investigators who have appointments in affiliated medical or engineering schools and who can communicate the results of VA research to students and colleagues.
- Through peer-reviewed research in the VA intramural program. Because competition for support is keen and the review considers the number and quality of publications and presentations at scientific meetings, there is pressure to disseminate information promptly to the research community, whether in the VA or outside.
- Through funded Rehabilitation R&D investigators, two-thirds of whom are involved in patient care and have direct professional interests in physically disabled veterans. Application of recent results can thus be direct (144).

Rehabilitation R&D also supports the Office of Technology Transfer, whose main responsibility has been preparing the *Journal of Rehabilitation R&D* (formerly the *Bulletin of Prosthetics Research*). The Office also maintains the Prosthetic Reference Collection and the Prosthetics Film and Audio-Visual Lending Service for interested researchers and clinicians (144).

## DISCUSSION

The goals and priorities of VA R&D are diverse, given its extremely broad mandates to address veterans' complex and difficult problems. VA R&D is especially important for rehabilitative devices, because the markets for many are small and fragmented. In the past, unless the stages of research, development, and transfer have each been publicly funded, market incentives have often been insufficient to ensure the availability of rehabilitative devices from private firms (109).

Table 2 summarizes the VA R&D budget. Although the commitment to R&D in current dollars has increased over the past few years (and substantially increased for Rehabilitation R&D in fiscal year 1983), the budget is stable or declin-

**Table 2.—Veterans Administration R&D Budget Overview** (thousands of dollars)

| | Fiscal year | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Medical research program | $101,567 | $108,153 | $118,016 | $122,745 | $129,943 | $130,842 | $141,052 |
| Staffing | 4,220 | 4,367 | 4,217 | 4,171 | 4,171 | 3,845 | 4,015 |
| Rehabilitation R&D program | 4,419 | 5,502 | 7,191 | 8,085 | 8,784 | 7,185 | 10,001 |
| Staffing | 69 | 90 | 112 | 143 | (143) | 128 | 250 |
| Health services R&D program | 3,604 | 2,996 | 3,004 | 3,153 | 3,083 | 2,828 | 3,786 |
| Staffing | 45 | 90 | 105 | 104 | 104 | 93 | 120 |

SOURCES: U.S. Veterans Administration, Office of Budget and Finance, *Congressional Budget Submission* (Washington, DC, 1983); R. Nolan, U.S. Veterans Administration, Office of Budget and Finance, Washington, DC, personal communication, September 1983.

ing when inflation is taken into account. Furthermore, as a proportion of medical care expenditures, funds for R&D have steadily declined for over a decade: In fiscal year 1970, R&D accounted for 3.4 percent of the total medical care costs, in 1982, only 2 percent (144).

Veterans' service organizations have expressed great concern about the effects of relative cutbacks in R&D budgets, especially those for prosthetics and sensory aids.

VAPC has encouraged innovation in the past by demonstrating that new types of wheelchairs were technologically possible, safe, and most importantly, that they had a significant market—the VA (80). The Center's work with power wheelchairs in the early 1970s showed they could be safely used at speeds greater than a slow walk and on rough terrain, which encouraged manufacturers to begin making such chairs. VAPC work on lightweight sports wheelchairs had similar effects. VAPC now focuses on commercially available devices rather than prototypes, which may change the VA's role in device innovation and development.

Especially given dwindling R&D moneys, the VA peer review and advisory council systems become even more important. The Medical Research Service has a well-developed merit review system, and both HSR&D and Rehabilitation R&D have restructured and improved their systems within the last few years. The Rehabilitation R&D process, modeled on that of the Medical Research Service, relies on in-house professionals, Rehabilitation R&D directors, and a multidisciplinary panel of non-VA experts to set research priorities and review proposals and results (109). Recently, Rehabilitation R&D has also taken steps to increase consumer involvement in planning R&D, placing representatives from veterans' service organizations on its merit review board.

Rehabilitation R&D, the primary focus of VA R&D on medical devices, deserves attention in at least two other areas. The first concerns Rehabilitation R&D Centers. Funding has shifted over the last few years to these Centers and their university-affiliated programs and away from extramural support. A 1981 VA evaluation of the two existing Centers concluded that they were developing toward a "stable and productive" existence, but noted some achievements were lagging (144). Delays were experienced in selecting Center directors, in completing basic construction and renovation, and in procuring essential computers and office supplies. Procurement problems have persisted, at least at the Palo Alto Center, which buys roughly $400,000 in devices annually (not including office supplies), because the Center must buy through the Palo Alto VA medical center procurement and supply service.

VA medical centers have relatively constant needs for medical equipment and supplies, but research centers, because of the nature of research, can exhibit highly erratic purchasing patterns. Research can also require highly sophisticated technology not normally purchased for medical care. Thus, the centralized contracting procedures used for medical center procurement may be inadequate for Rehabilitation R&D. Special contractual procedures can delay projects for a long time. The Palo Alto Center has reported equipment procurement lags of up to 18 months (53), longer than the duration of some Center projects.

The situation at the Palo Alto Center has been exacerbated by special VA procurement policies for microprocessor equipment. Much of the Center's work involves innovative uses of electronic and microprocessor technology. However, until recently all VA purchases of such equipment have been controlled by the VA's Central Office of Automated Data Processing. Even relatively unsophisticated circuit board devices costing $100 have needed approval not only of the local supply process but also of the Central Office.

Because of medical centers' increasing needs for automation, in May 1983 authority was delegated to the centers to procure all automated data-processing equipment, software, and services with a purchase value of $10,000 or less or a lease cost of $300 or less per month (53,122). Rehabilitation R&D has additionally designated smoother, more expeditious contracting procedures as one of its "special initiatives" beginning in fiscal year 1983 (152).

The second issue of interest regarding Rehabilitation R&D is that of technology transfer. For several years the VA had recognized deficiencies in the use of results from VA-sponsored R&D on rehabilitative devices. Generally, it seems that considerable information on new devices, techniques, and concepts had been disseminated, but there were no structured efforts to transfer technology (109). No system routinely promoted the greater use of successful prototype devices, which were known mainly through their experimental use in VA clinical settings (144).

Rehabilitation R&D has established an interagency agreement with the Department of Commerce to identify and develop potential markets and financing for prototype devices funded and developed through Rehabilitation R&D. The program's goal is to develop a better process toward commercializing VA technologies. In addition, the VA intends to improve its in-house testing and evaluation of prototype devices.

Although still in planning, Rehabilitation R&D's new initiatives in technology transfer are a significant step for the VA with regard to medical devices. Later chapters further examine the programs mentioned here, as well as the VA's role in technology transfer.

## Chapter 4

# Testing and Evaluating Devices

### Chapter 4

# Testing and Evaluating Devices

Testing and evaluation encompass many activities, including requesting, funding, and conducting studies. Techniques for testing medical devices are equally various, from the informal methods of individual inventors, developers, and physicians to complex clinical trials. No technique is applicable to every medical device, and in many instances simpler methods may be more appropriate. Often, researchers use a combination of techniques (7).

Depending on the nature of a device, public agencies, nonprofit organizations, and private firms also use different criteria to evaluate it. The most common, and perhaps most important, criteria used in the early development of health-related products are safety, technical feasibility, and technical performance. Depending on the use or intended market for a device, further test criteria may be effectiveness, suitability for designated goals, reliability, cost, cost effectiveness, repairability, convenience, esthetics, consumer satisfaction, patient protection, legal impacts, liability concerns, accessibility, reimbursement status, social implications, and ethical concerns (110).

Several Veterans Administration (VA) programs that evaluate innovations have evolved over the years given the many kinds of decisionmaking related to medical devices. The Rehabilitation R&D Service (Rehabilitation R&D) evaluates rehabilitative devices still in development. The Office of Procurement and Supply and the Prosthetic and Sensory Aids Service, along with other VA medical, surgical, and rehabilitative service offices, evaluate devices that are already commercially available but must be approved before the VA can purchase and distribute them.

## PROTOTYPE DEVICES

Rehabilitation R&D evaluates prototype devices and disseminates information, and in both cases works with the National Institute of Handicapped Research.[1] As noted earlier, the VA is mandated to test prosthetic, orthotic, and orthopedic appliances and sensory aids, and to disseminate information on its research for the benefit of all disabled persons (38 U.S.C. sec. 4101).

Still, rehabilitative devices often do not complete the transition from research prototypes to commercially viable products, even though Rehabilitation R&D supports dozens of ongoing device development projects. This discontinuity may be caused by several separate, but related, obstacles (which are discussed further in ch. 5). One of these obstacles is the lack of unbiased clinical evaluations of prototypes' performances and clinical applications (154). The VA explains this problem in a 1981 internal report (144):

> The problem is that, after the prototype has been developed, it is necessary to place a number of examples of the developed item into actual use, under conditions in which carefully controlled evaluations . . . can be carried out. Only after these evaluations, and any modifications which result from them, is it appropriate to manufacture such items for routine placement with veteran patients. In the case of other new health care developments (such as the development of new drugs) this evaluation phase is funded by the manufacturer's capital funds. In the development of new devices for the disabled, the developer (and/or proposed manufacturer) is frequently a very small business which cannot afford the capital outlay required to place a number of prototypes into an evaluation program . . . The Veterans Administration does not routinely purchase for its beneficiaries items

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[1] For discussion of the National Institute of Handicapped Research, see OTA's report *Technology and Handicapped People* (109).

> which have not been through testing and evaluation.
>
> . . . . the Research and Development budget is not adequate to provide the capital for purchase of expensive prototypes to be placed in actual use by veteran patients under an evaluation protocol. Similarly, it has not been customary to use patient care funds for this purpose. The only exception has been the purchase, by [the VA Prosthetics Center] . . . of devices which are put into evaluation protocols. There is currently no feasible alternative in the VA system available for those instances where, for whatever reason, the purchase and evaluation of the device by [the VA Prosthetics Center[2]] . . . is inappropriate. This situation has led to a number of instances where devices have been developed with VA research and development funds which subsequently neither have been demonstrated to be ineffectual nor have been put into general use by the veteran patient.

Expensive prototypes supported by VA R&D funding, but never evaluated, include the following (144):

- a wheelchair adapted for use with the Scott Van (a specially equipped van that can be driven by a person confined to a wheelchair or gurney), with a new system of electronic controls;
- a high-performance wheelchair developed at the University of California-Berkeley on contract;
- a wheelchair control system developed at the Johns Hopkins University Physics Laboratory on contract;
- a four-bar linkage knee for above-knee prostheses developed at the University of California-Berkeley on contract; and
- a standing device for paraplegics developed by Ocean Systems Laboratory in San Diego on contract.

Recently, Rehabilitation R&D has named its own evaluation unit to establish and operate a national program with the following goals (154):

> . . . . conduct clinical trials (or evaluations) on new devices, techniques and concepts in rehabilitation; promote commercialization of research devices evaluated by the program; and direct a technical information acquisition and dissemination program, which includes developing educational guidelines and technical manuals [for training programs].

The Rehabilitation R&D Service envisions the unit as a "facilitating and coordinating" center to improve the "organization and visibility" of the Service's evaluations. Various VA facilities, including Rehabilitation R&D Centers, the VA Prosthetics Center (VAPC), and individual medical centers, have been involved in testing and evaluating new and emerging rehabilitative devices through Service funding (154).

There have been concerns in the past, however, about duplication in testing and evaluating specific rehabilitative devices as they proceed from development to marketing and diffusion. For example, recreational ski equipment for the disabled person (later commercially produced as Arroya sit-ski equipment) was developed and tested at the Palo Alto Rehabilitation R&D Center and tested at four independent testing and evaluation centers. Still, it could not be purchased for veterans until VAPC had tested it again (5,6,53).

The Rehabilitation R&D evaluation unit is also intended to improve prototype testing and evaluation themselves through several means:

- developing uniform evaluation protocols and reporting procedures,
- developing criteria for patient or client selection,
- designating an appropriate number and the locations of facilities involved in particular evaluations,
- preparing and disseminating evaluation results, and
- integrating requirements of the Food and Drug Administration (FDA) and other regulatory agencies.

The unit generally oversees the evaluations performed. In simple cases, staff will negotiate arrangements. When an evaluation calls for a substantial national or international effort, a workshop may be held to bring together developers and evaluation professionals to work out arrangements. It is hoped that funding for major evaluations can be negotiated among all participants who have a stake in a device's development and ultimate commercial success (154).

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[2] Recall that the VA Prosthetics Center, as noted in ch. 3, primarily evaluates commercially available devices rather than prototypes.

It is premature to assess the Rehabilitation R&D evaluation unit. However, the program is important insofar as prototype testing and evaluation—in the clinic or in the community—can provide information on the likelihood of commercial success and indications for use, or information on changes that might lead to success. The information can also lead to more informed decisions about new research and development for rehabilitative devices (154).

## COMMERCIALLY AVAILABLE DEVICES

Any vendor who wishes to sell new medical devices, including equipment, supplies and expendables, and rehabilitative products, may have to submit the device for a product demonstration, "bench testing," or some other type of testing, to evaluate safety and various other criteria of the VA. New rehabilitative devices have traditionally been tested and evaluated by VAPC in New York City, and new equipment and supplies by the Testing and Evaluation Staff (T&E) at the VA Marketing Center in Hines, Illinois.

### The VA Prosthetics Center[3]

VAPC is a unique organization within the VA by virtue of combining programs in clinical practice—in prosthetics, orthotics, and technical aids—and programs in development and evaluation for their mutual benefit. New devices can then be used promptly in the clinic, as part of an evaluation or to study their wider applicability.

VAPC has long stressed in-house evaluation of commercial devices. It has been the VA's organizational focus for nearly all bioengineering and clinical evaluations of commercially available rehabilitative devices and for some hospital equipment for nearly three decades.[4] During its early years, evaluations concentrated on limb prostheses in response to the overwhelming needs of World War II veterans. In more recent years, evaluation has emphasized orthotics and the spinal-cord-injured patient. Evaluations in the 1970s emphasized bioengineering directed especially at the stroke patient, the patient with developing vascular insufficiency, and the aged person with problems of independence in daily living.

#### Standards Development

Throughout the 1970s, the VA increasingly employed standards in its prosthetic and sensory aids program. Developing standards requires not only evaluating devices in drafting the standards, but also compliance testing after the standards are established. In theory, compliance testing further tests the current standard and determines whether products meet the purchaser's needs. The standards developed reflected desired qualities of prosthetic and orthotic hardware, orthopedic aids, fitted limbs and braces, and sensory aids. "Specifications" of product attributes were included to control devices' quality, safety, and performance. Such standards were perceived as benefiting both VA beneficiaries and other disabled people. Once developed, standards were implemented through the VA Office of Procurement and Supply and its contracts with manufacturers and fitters.

VA standards development has required the participation of individuals and organizations both within and outside the VA. A draft standard of appropriate language can be developed from clinical experience with devices and techniques and the knowledge and experience of R&D and evaluation staff. The draft must then be evaluated by those who will work with it: manufacturers, prosthetists, orthotists, educational specialists, VA supply specialists, and others. Such reviews have also included professional associations such as the American Society for Testing and Materials, the International Standards Organization, and the Rehabilitation Society of North America.

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[3] Except where noted, information in this section is based on U.S. Veterans Administration, Department of Medicine and Surgery, *Veterans Administration Prosthetic and Sensory Aids Program Since World War II* (Washington, DC: U.S. Government Printing Office, 1978).

[4] VAPC's work has been complemented over the years by some evaluations of contractors, developers, manufacturers, and inventors of prototype devices, largely in weighing priorities for its own R&D.

Once a rehabilitative device standard has been employed, the VA—through VAPC—performs compliance testing of hardware, sampling the market and conducting laboratory tests. The VA makes known the results of such tests to its procurement personnel and to manufacturers.[5] When results of compliance testing have been negative, the VA has also developed engineering design recommendations.

VAPC has developed standards for lift aids motor vehicle systems for handicapped people, wheelchairs, knee mechanisms, foot-ankle assemblies, stump socks, elastic hosiery, crutches, canes, and other related devices. When VAPC has not developed a standard for a device, the VA Office of Procurement and Supply has relied, when possible, on other appropriate standards. The research and testing of the National Bureau of Standards (NBS) have been valuable to the VA in evaluation (18,109). NBS has developed devices to measure slip resistance on walkways, conducted performance and reliability tests on hearing aids and cardiac pacemakers, developed standards for acrylic bone cements and metals, and in general has helped address technical issues related to the needs of disabled individuals.

Veterans' organizations and others have expressed concern that the VA has used specifications and standards for existing technologies to evaluate and purchase new ones. Thus, emerging devices of unusual design or performance may have trouble entering the market, especially the large VA market (109). (Small firms may have pronounced difficulties since they have fewer resources to address regulations on marketing.) Older standards have been particularly vulnerable to such criticism, because they tend to specify product dimensions and materials.

Newer standards have emphasized, instead, functional or performance requirements. Precise materials, fabrication methods, and design features have generally not been specified. The goal has been to allow innovation while providing adequate controls for patient safety. At present, the VA has only four or five general standards for rehabilitative devices; for example, the standard for wheelchair lift systems covers 21 different models and 13 different manufacturers. Yet despite the VA's efforts, existing standards may still bar new technologies.

Shepard and Karon came to this conclusion in the case of wheelchairs (80). Historically, the VA's standards were written with a specific wheelchair, usually an Everest & Jennings model, in mind. The VA's evaluations of wheelchairs may have promoted safety, but they also functioned in the interests of the major manufacturers. As the largest purchaser of wheelchairs in this country, the VA might not only overlook new technologies, but possibly discourage innovation and product improvement.

In the last few years the VA has replaced most standards and device specifications with more general Commercial Item Descriptions (CIDs). CIDs are designed to accommodate better the variety of privately developed and marketed devices (see ch. 5 for a critical discussion of CIDs) (12).

### General Testing and Evaluation

VAPC device testing typically follows several preliminary steps (163):

- gathering background information, often from the manufacturer;
- developing an evaluation protocol that encompasses any appropriate VA standards and specifications as well as criteria to validate manufacturers' claims; and
- having the protocol approved by the R&D committees of any local VA medical centers involved in the trial.

Standardized protocols are also employed for certain general classes of devices.

Testing protocols range from simple validation assessments to complex clinical evaluations involving dozens of VA medical centers or clinics. At the least, rehabilitative devices are tested for safety, reliability, and the validity of manufacturers' claims. New wheelchair products, for example, are tested for strength, safety, maneuverability, and ease of use, although not necessarily for durability (18).

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[5] Manufacturers are prohibited by previous policy agreements from directly or indirectly using the results of VA evaluations for advertising (18).

Devices can undergo either special laboratory testing or field testing at VA medical centers or clinics, or both. Field testing is advantageous in assessing a device's "usefulness," that is, the conditions in which a device is most appropriately prescribed and used. Field testing also decreases the probability of observer bias by relying on a larger and more random group of testers. Yet VAPC has not always used field testing because of organizational difficulties.

Until fiscal year 1984, neither VAPC staff nor the VA Prosthetic and Sensory Aids Service, the primary users of rehabilitative device evaluations, had authority over researchers, in contrast to the case of VA testing and evaluation of medical equipment and supplies (see the later section of this chapter on VA Marketing Center testing and evaluation). This absence of authority typically resulted in lack of control over experimental protocols and data reporting, and often created an initial resistance to cooperating in device studies. Group evaluations, which compare similar devices, have been attempted but never fully developed (163), since they frequently involve extensive field testing.

VA evaluation of commercially available rehabilitative devices has been the target of complaints, especially from veterans' groups. The Disabled American Veterans organization has characterized the evaluation system as "fraught with inefficiencies and communication breakdowns" (160). In addition to the Disabled American Veterans' complaints, there have been other criticisms: that testing priorities are not adequately established and that there are long delays in evaluating devices; that clinical prescription criteria must be more standardized to ensure more consistent quality of care; that device needs of veterans must be better anticipated; and that devices should be evaluated by the FDA (not the VA) for safety (though by the VA for efficacy and cost effectiveness) (164).

### Prosthetics Technology Evaluation Committee

To address concerns about VA evaluations of commercially available devices, the Prosthetics and Sensory Aids Service established the Prosthetics Technology Evaluation Committee (PTEC) early in 1982. The committee—including representatives from the Prosthetic and Sensory Aids Service, the Office of Procurement and Supply, and Rehabilitation Medicine Services, the VA Inspector General's Office, and Rehabilitation R&D—has developed an evaluation and coordination process for VA products and devices, which is now almost fully operational.

PTEC will be responsible "for assessing and ranking the legitimacy and appropriateness of evaluation proposals and for assessing and approving the results of clinical evaluations" (125). The Prosthetic and Sensory Aids Service established PTEC primarily because of concern that the VA evaluation process was not sufficiently formalized. Not only were evaluation efforts hampered, but, faced with increasingly expensive devices and technologies and steady or declining budgets, the VA was using its lack of a process to deter supplying expensive prosthetic and sensory aids to veterans.[6]

The PTEC evaluation process probably has two main strengths: 1) classifying devices into three types to determine the testing and evaluation that devices will undergo; and 2) coordinating with other parties interested in rehabilitative devices, in the VA delivery system, other Federal agencies, independent testing labs, and veterans' groups. (The Paralyzed Veterans of America and the Disabled American Veterans, for example, both have permanent representatives on this committee. Other veterans' groups are informed of its activities and invited to participate in meetings.)

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[6] VA policy is to provide blind veterans with all necessary services and devices to overcome their handicaps and to provide other disabled veterans with devices and technologies deemed medically necessary. As in the case of disability compensation and pensions, a major concern to users and policymakers is the cost of covering all available technologies (62,109). This issue is discussed further in ch. 6.

The PTEC process groups devices into three types, according to potential risk, innovation, and (importantly) cost. It is like the FDA classification in determining the kind and extent of evaluation by a device's type. This classification system is not yet final. It will depend significantly on a survey of the users (which will also lead to prescription guidelines).

Generally, however, devices in the lowest category of risk, newness, and cost will seldom be subjected to laboratory testing other than the manufacturer's. Additional laboratory testing will concern only safety. Devices in the middle class will be laboratory tested, as needed, for compliance with existing standards, safety, and validation of manufacturers' claims. Provided the test results are positive, products will then undergo limited clinical trials to substantiate laboratory findings and to obtain users' opinions. Only devices at the highest level of classification will be subjected to extensive VA lab testing and clinical trials (22,50).

PTEC can provide information for various kinds of decisionmaking, from that of users to that of policymakers. To the extent possible, PTEC will rely on data from the FDA, independent laboratories testing, and others. The amount of testing information shared by the VA and the FDA has traditionally been negligible, however. Evaluation criteria have generally differed because of the VA's special needs and client population. The VA has also been hesitant for the FDA to use VA data because private device manufacturers might request free evaluation services from the VA (50).

## Testing and Evaluation Staff, VA Marketing Center

At any one time, about 250 devices, ranging from hospital-based equipment to supplies and expendables, are being reviewed by the VA Office of Procurement and Supply as a requisite for procurement contracts. The Office's Testing and Evaluation Staff (T&E), part of the VA Marketing Center and supply depot in Hines, Illinois, has primary responsibility for this aspect of VA device testing.

The T&E was established in February 1976 by administrative fiat, based on a VA-initiated study, the "McKinsey report." The study suggested that the VA might perform several functions (57):

- be a valuable source of information on medical devices for other health care providers,
- centralize and expand existing information and evaluation activities,
- support the FDA in ensuring the safety and efficacy of medical devices, and
- stimulate the development of new or improved products for identified needs.

As the McKinsey report was released, the FDA also entered a memorandum of understanding with the VA to exchange medical device "experience." This agreement would eventually require a VA clearinghouse for medical device recalls from the FDA and hazard reports from VA medical centers. Meanwhile, the McKinsey report's recommendation to stimulate innovation was implemented with the help of NBS, which initiated the Experimental Technology Incentives Program (ETIP). The VA agreed to participate in market research to promote public or private partnerships and industry incentives to develop medical devices. ETIP, first placed in the VA Central Office, remained dormant for a year. With the establishment of T&E, however, ETIP was transferred to the VA Marketing Center with a grant of $450,000. As a result of all these events, T&E has had responsibility for medical device evaluations, liaison with FDA on recall and hazard alerts, and ETIP (134). The ETIP-VA agreement ended in 1981, but T&E has continued its market research.

Testing and evaluating VA-purchased medical devices is T&E's central focus. Such medical devices are selected for evaluation through requests by VA medical centers, manufacturers, the VA Central Office, and "in-house" initiatives. Choices depend more on volume considerations and the interest of VA health care facilities than, for example, cost factors (67).

Once a device is selected for testing and evaluation, prospective clinical trials may be carried out under the auspices of the Medical Research Service (18) or cooperatively with the Department of Defense through an agreement with Fort Sam

Houston in Texas. Most often, however, testing and evaluation consist of internal consumer research to validate manufacturers' claims with tests carried out at VA medical centers and facilities around the country. T&E also has working agreements with nearly a dozen private testing laboratories, for needed laboratory tests, including the Emergency Care Research Institute, Utah Biomedical Laboratories, Stanford Research Institute, and Underwriters Laboratories. Information is also shared with some of these laboratories (134).

T&E develops the base protocols, which may be amended by appropriate medical services within the VA. Testing sites are also cooperatively selected, with local VA supply and procurement officers administering hospital tests (67). As the appropriate VA manual specifies (156), evaluations typically take the form of user surveys on many product features, including compliance with manufacturers' claims and industry standards, safety, design, ease of use, durability, cost, and the products' advantages and disadvantages compared to similar products.

Testing may last from 2 weeks to a full year, but averages 30 to 60 days. Information is then compiled in a brief description of the product (often derived from manufacturers' literature) and of survey findings. The Office of Procurement and Supply publishes evaluation results quarterly and distributes them to VA medical centers, medical and regional office centers, clinics, and supply depots and distribution centers, and to procurement officers at the VA Marketing Center. Results of the evaluations cannot be used by manufacturers, but they are routinely requested by private hospitals, nursing homes, and State and local governments, and are reprinted by private publications such as *Consumer Reports*, *Hospital Purchasing Management*, and *Health Devices Alert* (18,67,147).

Importantly, evaluations are *advisory*. Theoretically they are incorporated in national procurement contract requirements, but purchases are not based solely on the evaluations. Purchasing decisions still rest with individual hospitals, which, on average, purchase from national contracts only about 60 percent of the time. Furthermore, evaluations stress advantages and disadvantages based on a manufacturer's standard or claim. There are no evaluations of features for which manufacturers make no claims. VA regulations also prohibit explicitly comparing one product with another. There have been efforts to do group evaluations of some classes of devices. Group evaluations would better control for testing bias and could generate more meaningful information. Staffing and budgetary restraints, however, have restricted T&E to very few group evaluations (67).

T&E primarily evaluates standard stock items and smaller medical equipment. Decisions to purchase expensive devices, for example computed tomography (CT) scanners, involve not only supply and procurement staff; they require the approval of special medical equipment committees in individual medical centers and that of Service Directors in the Central Office.[7] Although there are a few exceptions, Service Directors have traditionally relied only on data generated by the manufacturer or on VA "acceptance testing," which prospectively establishes "performance requirements" (e.g., for reliability, dosages, or performance times). with local interdisciplinary VA teams assessing devices against the criteria. The Medical Research Service has worked jointly with other Services in some evaluations. For example, the Radiology Service made purchasing decisions about CT scanning with the help of an advisory committee including the directors of medicine, surgery, neurosurgery, and neurology. Two research projects—one comparing the costs of inhouse scanners and those of contracting for scans and another evaluating VA hospitals' sharing of CT scanners—also figured in these decisions.

Recently, manufacturers have begun to offer the VA expensive equipment outright in exchange for exclusive long-term contracts for disposables the hardware requires or in exchange for experimental data. The VA now lacks a policy on accepting or using such equipment (18).

In fiscal year 1983 T&E began postmarketing surveillance by surveying all VA purchasers and users of products previously evaluated. The survey's goal is to determine performance, quality, and other product characteristics after more prolonged use. Two dozen items are to be reviewed each year. Summaries of responses will be published quarterly along with new product evaluations (67,133).

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[7] Expensive medical and dental equipment, generally items above $30,000 and others specified in VA regulations (157), are called "controlled items." Controlled items are further discussed in ch. 6.

T&E is also concerned with "product assurance," resolving medical device and product complaints and providing staff support for developing specifications, standards, and inspection criteria for equipment and supplies bought centrally and managed by the VA depot system (which is described in ch. 5). For example, T&E has developed standards for hospital beds and eyeglass frames, the last jointly with ETIP.

To the extent possible, T&E and, in turn, procurement components of the VA have relied on existing standards and device evaluations, such as those of the FDA's National Center for Devices and Radiological Health in the area of radiation leakage (18). The VA also wants to rely on FDA standards and testing if the provisions of the 1976 Medical Device Amendments on performance standards are implemented (13). If a device has been on the market for some time, the VA will often use any evaluations conducted by NBS and the Department of Defense (18).

The current Administration is also moving toward voluntary standards as an official policy in all areas. Office of Management and Budget Circular A-119, currently in effect, describes the use of voluntary standards for procurement. T&E has worked with several voluntary standards groups in the past, including the American Society of Testing and Materials and the National Sanitation Foundation. As an alternative to using standards, the VA has increasingly used CIDs, which are adopted as standards are, but allow a broader mix of devices to be purchased. So far CIDs have had a much greater impact than standards in the purchase of medical devices (67), as discussed in the following chapter.

The VA requires its medical centers to use depot-stocked items when possible. To ensure user satisfaction, the VA has a formal system for registering complaints with the VA's Marketing Center, which must promptly resolve these complaints.

A 1982 General Accounting Office (GAO) report called for this system to be improved (101). Medical centers, it found, were not satisfied with depot-stocked items and often bought alternative products from other sources without filing a complaint. As a result, inferior stock was often not brought to the Marketing Center's attention. When complaints were filed, the Marketing Center often did not take appropriate action, further discouraging medical centers from reporting complaints.

The medical centers use the VA's Quality Improvement Report to file complaints about depot-stocked items. During fiscal year 1980, for example, 478 Quality Improvement Reports were filed on medical supply and equipment items. However, until fiscal year 1982, the marketing and procurement officers ("commodity managers") at the Marketing Center were also responsible for responding to Quality Improvement Reports. GAO felt that the commodity managers perhaps could not evaluate reported problems objectively. With regard to frequently registered items, GAO found that the Marketing Center: 1) did not address the medical centers' stated problems, 2) did not provide the medical centers with clear resolutions, or 3) provided the medical centers with false assurances.

In response to the GAO report, the VA transferred responsibility for the quality complaint system to the Marketing Center's T&E staff beginning in fiscal year 1982 to improve the system's objectivity and responsiveness. Transfer to T&E of the quality complaint system had the additional benefits of coordinating evaluations and encouraging better information exchange with the FDA on medical device problems and experience. All Quality Improvement Reports received by T&E are screened to determine the potential for hazard alerts or product recalls because of risk to the lives or safety of patients and employees. T&E forwards information on hazard alerts to the FDA's National Center for Devices and Radiological Health and other divisions of the Marketing Center, which in turn notify all VA medical facilities.

Another function of T&E is developing and managing a computerized information storage and retrieval system for consumers. Another outgrowth of the VA-ETIP program, this system facilitates the flow of information among the purchasing divisions of the Marketing Center, VA medical centers, and other Government agencies; provides product, price, and vendor histories useful in awarding VA procurement contracts; and contains marketing data useful and available to private manufacturers. Since larger companies often have in-house marketing capabilities the information has been most useful to smaller and emerging companies.

## DISCUSSION

This chapter has focused on the VA's diverse evaluation activities. Generally, VA evaluations are conducted during the later phases of R&D. Late in the R&D process is generally when information must be collected for reimbursement, financing, and drug and device regulation (i.e., for decisions affecting use). This is a good time for evaluations insofar as information and experience may be available and the device has not yet been widely diffused. Evaluations can then affect the VA's adoption of devices (109).

The separation of Rehabilitation R&D from other VA research in 1973 was partly to give more focus to VA rehabilitation research (109). In turn, this focus helped stimulate the VA to devote more attention to evaluation, as in establishing the Rehabilitation R&D evaluation unit.

At the same time, one veterans' group has criticized the divided responsibility for evaluation. Commercially available devices, especially rehabilitative ones, often need refinements before the VA can approve them for its use. According to the Disabled American Veterans, in these cases it may not be clear who is responsible for evaluation—Rehabilitation R&D, Prosthetic and Sensory Aids Service, or the VA Office of Procurement and Supply (160).

Coordinating evaluations has been addressed by forming PTEC. In calling for the involvement of all relevant VA services and in inviting consumer groups to participate, the VA appears to be taking a step toward more systematic evaluation of rehabilitative devices. PTEC has the support of such groups as the Paralyzed Veterans of America and The American Legion (71,82).

Thousands of rehabilitative devices issue from the public, private, and nonprofit sectors. Many are relatively simple and inexpensive, and others are costly and complex. Regardless of a device's cost, complexity, or proposed use, it should meet certain criteria before being widely used, notably those covering safety, effectiveness, durability, and recommended applications (112). Baseline assessments combine laboratory testing and clinical evaluations. Some devices warrant much broader assessments. Costs should be explicitly considered in some cases. In others, evaluating the devices in the user's environments may be essential (109).

Both the Rehabilitation R&D evaluation unit and PTEC would seem to embrace these testing needs. Both programs are new, however, and there are problems yet to be resolved. PTEC, for example, needs to expand its field testing activities and to make its testing more national in scope. PTEC's authority over VA medical facilities should be established internally. The Rehabilitation R&D evaluation unit could encourage more testing and evaluation at Rehabilitation R&D Centers and ensure that its results are valid and credible to PTEC, to avoid duplication of efforts. Even with these problems, the evaluation unit and PTEC appear to have great potential.

In evaluating medical equipment, supplies, and expendables, T&E represents a modest but productive effort, given its small staff. Although not rigorous, its evaluations can provide information for purchasing by VA facilities. T&E evaluations are apparently most often used by smaller, more rural VA facilities. The VA estimates that only about 20 percent of its medical centers make purchasing decisions based on T&E evaluations. At the same time, supply and procurement officers at all VA hospitals use the evaluations as an information resource, including in doing business with vendors.

Although T&E evaluation generally does not study such features as cost effectiveness, it could do so through more group evaluations with modest increases in budget and staff. Its publications of results and standard setting can have significant influence because of the VA's market power. For example, the VA's requirement that fibrillating catheter devices for the heart meet National Fire Protection Association Standards led to complete industry compliance in manufacturing these devices, despite the absence of industry consensus (46). VA publication of testing results on hearing aids spurred innovation and competition among manufacturers (41). (The VA Office of Procurement and Supply has occasionally been reluctant to publish its test results, however, because the demographic characteristics of the veteran population are not always those of all consumers (18).)

It is noteworthy that large private buyers such as for-profit hospital chains have developed organizational components similar to T&E. At the recommendation of a private third-party payer, the Hospital Corp. of America recently announced the formation of "product standardization" committees to evaluate products' "safetyworthiness," failures, and performance, and to manage product recalls—all tasks of T&E (69). Special evaluation groups may be valuable to large medical systems.

T&E's weakness may lie in not integrating evaluation information and its market research into the overall VA marketing, procurement, and supply system. This issue is considered more fully in the next chapter.

## Chapter 5

# Marketing, Procuring, and Supplying Devices

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# Marketing, Procuring, and Supplying Devices

The Veterans Administration (VA) both promotes and purchases medical devices, necessitating different kinds of VA programs. As part of its commitment to research, development, and evaluation of rehabilitative devices, the VA's Rehabilitation Research and Development Service (Rehabiliation R&D) works with private organizations in manufacturing and marketing products they have developed. The VA Marketing Center (VAMKC), in the VA Office of Procurement and Supply, on the other hand, determines the VA's need for commercially available devices and purchases and supplies these devices.

The VA activities related to prototype rehabilitative devices, which are discussed here first, by definition conclude at the marketing stage. VA activities related to commercially available devices (rehabilitative devices and equipment and supplies), which are described later, encompass marketing, procurement, and supply.

## PROTOTYPE DEVICES

Technology transfer is generally one of the more difficult hurdles in developing and distributing rehabilitative devices. Chapter 3 touched on the VA's long absence of structured activities in this area. No VA system routinely ensures that successful new prototypes are transferred to clinical practice.

There are a number of significant obstacles to private industry's participation in this process as well (65,109):

- lack of adequate demographic data (or market statistics) about the technologies disabled people need;
- the commercial vulnerability of some ventures because of small, fragmented markets and high investment costs; and
- obstacles presented by the patent system, liability insurance requirements, and the third-party payment system.[1]

Figure 5 illustrates the generally complex dynamics and requirements of private sector efforts to bring research ideas, information, and products to the consumer.

One purpose of the Rehabilitation R&D Center's evaluation unit is to address the problem areas of marketing and finance, which it plans to do in at least two ways (154):

- by encouraging device development and innovation to meet disabled veterans specific needs, and
- by helping VA-supported researchers and appropriate industry representatives coordinate an interagency program with the Department of Commerce for commercializing prototype devices that the unit evaluates.

The VA Administrator signed an interagency agreement with the Department of Commerce in May 1983, and the VA planned to reimburse the Department for up to $125,000 in fiscal year 1983 for its expertise in marketing and commercializing technology.

The VA is also considering a specific program with the Department of Commerce like the Na-

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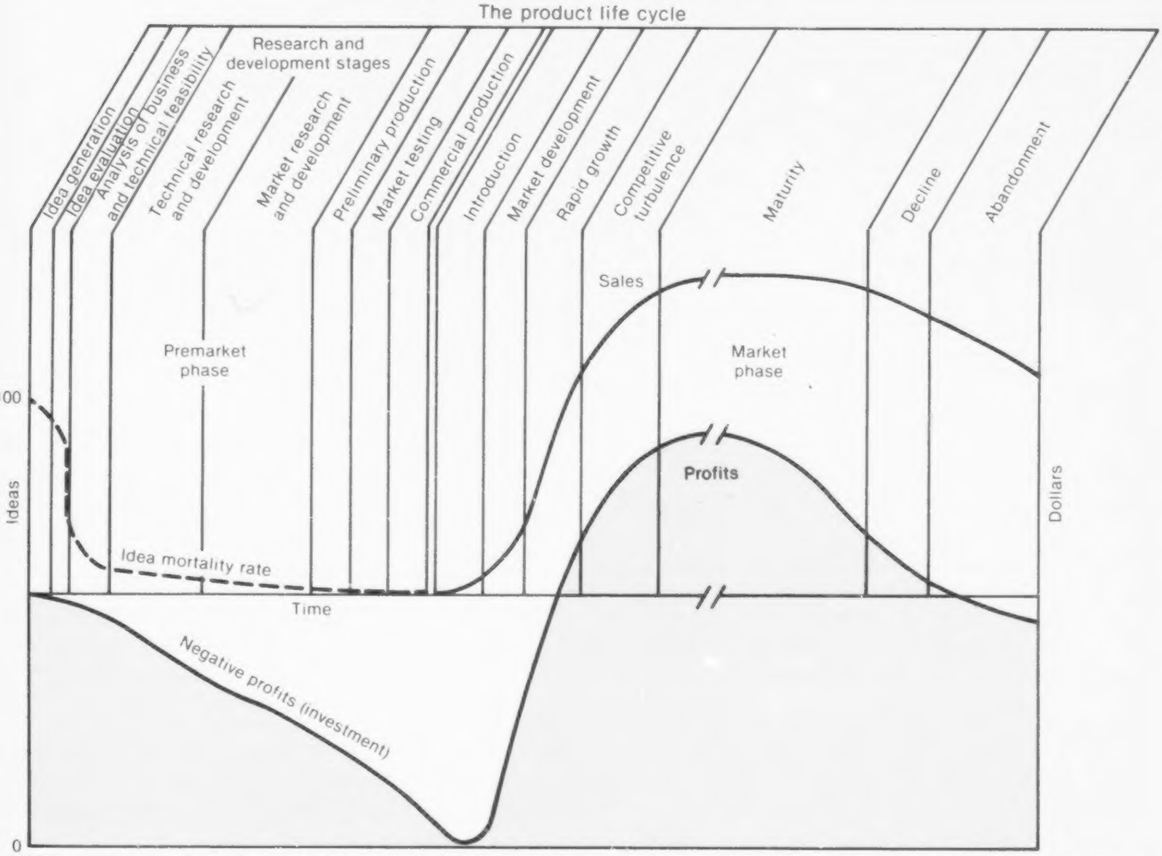
[1] A further problem, discussed in ch. 4, results from the VA's being both a large market for many devices and an arbiter of performance and design standards. To a large extent the VA can thus determine which technologies enter the market. If the VA uses specifications and standards developed for existing technologies, it may impede the emergence of innovative devices.

Figure 5.—The Innovation Process



SOURCE: J. E. Muthard, "Putting Rehabilitation Knowledge to Use," Rehabilitation Monograph No. 11 (Gainesville, FL: University of Florida Rehabilitation Research Institute, 1980), as cited in (109).

tional Science Foundation's Small Business Innovation Research Program. Funding of up to $20,000 would be provided to small businesses to "demonstrate the feasibility of a new concept." When feasibility studies have been done, the program may support a limited number of more substantial proposals to carry new concepts through prototype testing and evaluation. The program would be directed at established, specific needs of disabled veterans (154).

Another purpose of the evaluation unit is to improve the link between the VA's R&D and industry by several means (154):

- monitoring the progress of all Rehabilitation R&D projects on devices;
- staying informed of any links Rehabilitation R&D projects have with industry, and encouraging industrial interest where there is none;

- developing information on U.S. and foreign industry that relates to disabled veterans, and accessing data stored in VA banks and in ABLEDATA;[2] and
- coordinating the Rehabilitation R&D interagency agreement with the Department of Commerce in market surveys, locating capitalization funds, and stimulating the commercialization of R&D prototype devices based on its evaluation program.

The Rehabilitation R&D Center's evaluation unit can substantially increase, centralize, and improve Rehabilitation R&D's role in marketing and financing, though until now efforts have been piecemeal. The Rehabilitation R&D Center at Palo Alto, for example, has retained an in-house marketing specialist since December 1982. The Palo Alto Center is now working with about 30 companies in developing devices.

Nevertheless, the evaluation unit does not necessarily solve all problems of technology transfer. The Palo Alto group ran into difficulties because of Public Law 96-517, concerning patent rights to inventions developed by nonprofit institutions using Government funds. The VA will not implement the law for several months, although other Federal agencies that fund R&D already have. In the interim, Stanford University (whose engineers work with the VA at Palo Alto) has been unable to file a patent application to protect its intellectual property rights on at least one prototype device.[3] Instead, Stanford has requested that the engineer-inventors participate in VA patent evaluation and application filing and has encouraged the VA to conduct its investigation of the device "with due speed, so that the publication ban will not post before a patent filing decision is made" (53,76).

## COMMERCIALLY AVAILABLE DEVICES

### Marketing

The VA's Marketing Research and Analysis program, developed from the VA-National Bureau of Standards Experimental Technology Incentives Program during the late 1970s. It represents a major change in VA procurement in bringing marketing judgment to bear on commercial products' entry into the VA supply system and is central in developing VA procurement strategies. Marketing Research and Analysis is primarily the responsibility of the Testing and Evaluation Staff (T&E) of the VAMKC, although each procuring division of the VAMKC has a product development section supporting the program (128).

As a purchaser of devices, the VA attempts both to obtain the lowest possible prices in contracting and to improve medical care. Marketing Research and Analysis is a resource for procurement by gathering and analyzing information on the range and quality of available commercial products and determining whether they meet VA needs. This is done through surveys, Quality Improvement Reports (discussed in ch. 4), and other techniques ranging from informal telephone inquiries (about products acquired by local medical centers) to comprehensive reviews (of products that may improve care VA-wide or effect substantial savings) (130). The aim of this product and market research is to determine the need, demand, and best method of supply for items. Recommendations are then forwarded to procurement officers.

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[2] ABLEDATA is a new computer information system funded by the National Institute of Handicapped Research as a service of the National Rehabilitation Information Center based at Catholic University, Washington, DC. ABLEDATA combines manufacturers' data and updated information on local availability of products, names of manufacturers, locations of distributors, product descriptions, costs, and results of any relevant evaluations. The data bank is accessible to information brokers at locations around the country, and the brokers are accessible to rehabilitation centers, individuals, or anyone who needs the information. The Prosthetic Technology Evaluation Committee (discussed in ch. 4) also plans to share information routinely with ABLEDATA (109).

[3] A recently named property right distinct from patents, copyrights, trademarks, and trade secrets is "tangible research property." For example, in March 1982 Stanford University developed a special policy on tangible research property to protect its ownership of "tangible (or corporeal) items produced in the course of research projects," including "biological materials, computer software, computer data bases, circuit diagrams, engineering drawings, integrated circuit chips, prototype devices and equipment, etc." (83).

This VA program encompasses research in many areas (130):

- product research (on products satisfying VA and other users' needs, product changes required to meet VA needs, product descriptions used in commercial transactions, and new products needed);
- market analysis (on the number and competitiveness of firms, business practices, pricing structures, distribution practices, restrictions on shelf life and storage);
- analysis of the commercial market (on acceptability to likely users in light of such features as reliability and warranty); and
- analysis of product support (on warranty and support procedures).

Such research originates from the VA Central Office, procurement offices at the VAMKC, and T&E.

An obvious priority during the program's first years was to test the hypothesis that because of its size Federal procurement could significantly influence market innovation by providing an early market for products, thus reducing market entry risks (52). Results of this test were mixed.

For example, the program authored the *Directory of Living Aids for the Disabled Person*, having found that no single printed source of such information existed although there was a corresponding demand. Publishing firms were solicited to determine their interest and the feasibility of the endeavor. As an incentive to industry, the VA proposal called for the directory to be published once for distribution to people within the VA health care system but allowed the contractor or any other interested parties to use the same data commercially, with obvious private as well as social benefits. The VA objective, which was reflected later in the publishers' bids, was to have bidders recognize the directory's market potential and publish it at minimal cost to the VA (67).

The program's projects have not always been so successful. Another project determined that syringe needles should be more readily destroyed for disposal. Working closely with a small private firm, the program helped develop such a product, but the company eventually went bankrupt (67).

More recently, the program has focused on commercially available products. Criticism of products, poor depot sales, and seeming technological breakthroughs are typical subjects of research. T&E also frequently relates its testing and evaluation, Quality Improvement Reports, and recall and hazard alerts to the program's research (67).

## Procurement and Supply[4]

The VA's Office of Procurement and Supply supports the most extensive medical program in the Federal Government and also provides nonperishable subsistence supplies, medical equipment and supplies, drugs, biologicals, reagents, and chemicals to more than 4,100 installations of other Government agencies. These services are supported by nearly 6,800 employees, including staff at the Central Office, the VAMKC, three supply depots, the Prosthetics Distribution Center, and 172 medical centers.

In fiscal year 1982 the VA's Office of Procurement and Supply spent nearly $1.3 billion on supplies and equipment. Two kinds of mechanisms support this procurement and delivery: the VA's central procurement programs, and the local supply activities of medical centers. Generally, central procurement encompasses all medical equipment, supplies, and rehabilitative device items, while local purchases are usually of disposable medical and dental supplies.

### Central Procurement

Several centralized VA procurement programs have been established over the years so that individual medical centers can obtain supplies and equipment economically, not having to solicit and award contracts themselves. The VA finances all supply operations through a revolving supply fund, charging customers a percentage markup over the item's purchase price, about 6 percent, to balance the fund (99). The VAMKC provides these centrally managed supply channels, which are also available to other Government agencies, such as Public Health Service hospitals, the Bureau of Indian Affairs, and Federal correction institutions.

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[4] Except as noted, this section is based on U.S. Veterans Administration, *Brief of Office of Procurement and Supply*, unpublished (Washington, DC, December 1982) (121).

Centralized procurement programs are organized into procurement divisions, each headed by a commodity manager, specializing in different areas: pharmaceuticals, medical supplies, medical equipment, surgical supplies, and nonperishable subsistence supplies. These VAMKC programs include a national depot distribution system, Federal Supply Schedules (FSS) for items that the General Services Administration assigns to the VA to manage, contracts for direct delivery to medical centers, and decentralized contracts for direct ordering by medical centers.

### VA Supply Depots

During the 1940s, wartime demands and poor distribution systems made it necessary for the VA and the Department of Defense (DOD) to establish depot inventories of hospital stock. These depots have been continuously maintained to the present day (34). Under this program, volume purchases are made at low prices and items are managed through three VA supply depots, in Somerville, New Jersey; Hines, Illinois; and Bell, California. A Prosthetics Distribution Center in Denver, Colorado, also serves the approximately 200,000 veterans with service-connected disabilities.

Medical center supply requests are transmitted to the VA's Data Processing Center in Austin, Texas, recorded in the automated supply system (the Integrated Procurement, Storage, and Distribution System, or "Log 1"), and then sent to the appropriate depot to be filled. In fiscal year 1982, VA medical centers obtained about $198 million in about 650 different supply and equipment items (over 95 percent supplies) from the supply depots. Depot shipments and receipts are also recorded in Log 1 for the VAMKC's management of depot stock (100).

### Federal Supply Schedules

Under the FSS program, Government agencies contract with commercial vendors for many supplies and services. The schedules allow VA medical centers and other agencies to order directly from contractors at preestablished prices.[5] The VAMKC manages FSS contracts for certain drugs, chemicals, subsistence supplies, and medical supplies and equipment (the General Services Administration manages VA FSS contracts for such items as furniture and office supplies and equipment) (100). In fiscal year 1982, VA medical centers purchased materials worth about $434 million through this program. Table 3 gives a more specific breakdown of FSS purchases for selected devices.

### Decentralized Contracts and Direct Delivery

The VAMKC also administers decentralized contracts for medical centers. These contracts are for specialized medical equipment, for example,

**Table 3.—Selected Device Purchases by the Veterans Administration Using Federal Supply Schedule Contracts, Fiscal Year 1983[a]**

| Items | Expenditure (millions of dollars) |
|---|---|
| Medical supplies (mainly consumables) | $120.0 |
| Dental supplies and equipment | 17.5 |
| Medical supplies and equipment | 46.7 |
| Pacemakers | 5.0 |
| Wheelchairs | 9.6 |
| Surgical gloves | 1.3 |
| Eyeglasses | 1.3 |
| Medical X-ray film | 6.0 |

[a]Estimated.

SOURCES: U.S. Veterans Administration, *1982 Annual Report* (Washington, DC, 1983); U.S. Veterans Administration, *Brief of Office of Procurement and Supply*, unpublished (Washington, DC, December 1982).

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[5] The schedules contain a "buy American differential" clause. Essentially, a price differential (percentage) must be applied to a foreign-made item before placing an order if foreign and domestic products are listed under the same special item number in the FSS and both products satisfy an item requirement (148). This discourages purchase of the foreign-made item unless the price of the U.S.-made item is higher by a certain percentage.

electrocardiograph and stress test equipment, sterilizers, pacemakers, and intravenous pumps, which are usually not available through the depot or FSS programs. VA medical centers are the primary users of this program, but other Government agencies may participate. For direct deliveries, the VAMKC not only administers contracts but also orders for the medical centers. Vendors then deliver material to them directly. This program is used primarily for radiological and nuclear supplies and equipment (100). In fiscal year 1982 these two programs accounted for $158 million in medical center purchases.

### Other Activities

The VAMKC directly procures medical supplies for other Government agencies including the Agency for International Development, the Bureau of Indian Affairs, DOD, the U.S. Air Force in the Philippines (CT scanners), the U.S. Army in Germany, the U.S. Army Medical Materiel Agency (nuclear diagnostic equipment for world wide distribution), and the U.S. Embassy in Moscow. In addition, the VAMKC has processed 2,600 individual orders for direct delivery to various Army hospitals within the 48 contiguous States and has provided radiographic equipment for U.S. health services in the Virgin Islands. In fiscal year 1982 the total value of this direct procurement was $15 million.

The VAMKC also participates in the Medical Shared Procurement Program with DOD, one of many Federal interagency agreements for sharing or exchanging materials, facilities and services.[6] Commonly used items are procured by one agency to secure the best possible price, while simplifying procurement for both the agencies and private firms. As of July 1983, the total annual dollar value of contract awards under the VA-DOD program was $295 million.

The VA has executed over 200 supply agreements with 17 other Federal agencies worth $45.2 million per year in exchange for support services. Of the $45.2 million, $33.7 million represents VA supply support to other Federal facilities. Table 4 shows the source, dollar value, and type of supplies provided during fiscal year 1982. The remaining $11.5 million represents the coordination or exchange of medical, laboratory, and laundry services; automatic data-processing systems; research and development projects; maintenance of facilities, roads and grounds; and training.

Finally, the VA has established an Office of Small and Disadvantaged Business Utilization as part of a larger Federal program that reserves some procurement for the exclusive bidding of small and minority-owned businesses. The program was designed to give these businesses equal opportunity to compete for Government contracts and subcontracts (102).

### Medical Center Supply Activities[7]

All VA medical centers have similar supply and procurement characteristics. Generally, each center has its own supply service that acquires and distributes supplies and manages center inventories. In a few metropolitan areas, centers share a supply service and warehouse.

The departments within a center, such as dietetics, engineering, radiology, and pharmacy, or-

**Table 4.—Veterans Administration Supply Support to Other Federal Facilities, Fiscal Year 1982**

| Items | Costs (dollars) |
|---|---|
| ***From VA depots:*** | |
| Drugs and medicines | $ 8,776,006 |
| Other medical supplies | 5,335,163 |
| General supplies | 332,437 |
| Subsistence supplies | 6,869,817 |
| Equipment | 11,177,690 |
| Subtotal | $32,481,113 |
| ***From field stations to:*** | |
| Territorial governments | $ 371,980 |
| Other government agencies | 803,861 |
| Subtotal | $ 1,175,841 |
| Total | $33,656,954 |

SOURCE: U.S. Veterans Administration, *Brief of Office of Procurement and Supply*, unpublished (Washington, DC, December 1982).

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[6] Agreements have developed pursuant to the Economy Act of June 1932, as amended (31 U.S.C. 1535); Public Law 97-258, September 1982, as amended; and Public Law 97-332, October 1982.

[7] Information in this section is based on U.S. Congress, General Accounting Office, *VA Needs Better Visibility and Control Over Medical Center Purchases*, PSAD #81-16, Washington, DC, Dec. 12, 1980 (100).

der through the center's supply service. The supply service is required to fill requisitions appropriately and promptly, ensuring that vendor competition is adequate and prices are reasonable. Expendable supplies received by a medical center are either stocked in the center's warehouse (posted) or delivered directly to the appropriate department (unposted).

The VA's automated supply system provides information for medical centers, as well as the VAMKC, to use in procurement. The medical centers contribute data on their stock orders, receipts, and distribution, and use Log 1 to manage local stock, whereas the VAMKC uses this information not only to manage depot stock but to identify posted items with central management potential. Log 1 has files on three types of medical center procurements: expendable posted and unposted supplies and nonexpendables (equipment).

As described above, the VAMKC centrally manages items commonly used by VA medical centers and provides several centrally managed supply channels, but it purchases very little directly for the centers. The VAMKC mainly selects items based on medical center usage, on the assumption that it can obtain lower prices and more reliable sources than individual medical centers can. VA priorities for sources of medical center supplies are listed in table 5.

To ensure proper supply channels are selected, the VA requires that the medical centers' supply services review each purchase request. The open market may be used to purchase items not available from centrally managed (so-called mandatory) sources, when they are needed for an emergency or are available at lower prices than through FSS.

## The VA's Impact on Product Quality

An important responsibility of the VAMKC is ensuring product quality. This responsibility has proved difficult to fulfill. In fiscal year 1980 the VAMKC began using Commercial Item Descriptions (CIDs) in place of more detailed product specifications and standards to purchase medical supplies and equipment, in response to a new Federal procurement policy to "purchase commercial products and use commercial distribution systems" whenever possible (117).[8] CIDs and purchase descriptions (the latter used only for small or special purchases) are simplified product descriptions of the functional or performance characteristics of commercial products acceptable for Government use (115). These descriptions are still to ensure that items purchased are satisfactory.

A 1982 General Accounting Office (GAO) study found that the VA had applied the new policy improperly (101). The VA's purchase descriptions were only one or two sentences long and

**Table 5.—Priority Purchasing Sources for VA Medical Centers**

| Supply channel | VA priority ranking | Approximate annual purchases[a] (millions of dollars) | Percentage of total |
|---|---|---|---|
| VA excess | 1 | NA[b] | NA[b] |
| VA supply depots | 2 | $197.9 | 15.3% |
| Other government excess | 3 | 0.4 | — |
| Federal prisons and correctional institutions, blind-made and severely handicapped products | 4 | 1.0 | 1 |
| General Services Administration stock | 5 | 34.1 | 2.7 |
| VA decentralized contracts | 6 | 41.4 | 3.2 |
| Federal Supply Schedule contracts | 7 | 434.4 | 33.6 |
| Open market purchases | 8 | 498.2 | 38.5 |
| Other | None | 86.0 | 6.6 |

[a] Fiscal year 1982.
[b] Not available.

SOURCE: U.S. Veterans Administration, *Brief of Office of Procurement and Supply*, unpublished (Washington, DC, December 1982).

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[8] VA specifications were detailed documents, typically covering design, materials, workmanship, and other product features; sampling, testing, and inspecting procedures to be used; packaging and marketing requirements; and other measures to determine whether a product qualified for purchase. Specifications are not to be confused with standards, which typically include only a product description and performance requirements. However, specifications often incorporated standards (12).

contained little specific information. In addition, GAO concluded that in developing purchase descriptions, the VAMKC marketing divisions did not communicate with users and suppliers. As a result, the VA purchased many medical items that were either unneeded or inferior.

GAO also found other problems in the new CID system. Before using CIDs, the VA had relied on three elements for quality control:

- the marketing division, through its specifications, standards, and qualified products lists;
- the depot inspectors, through inspections upon delivery; and
- individual medical centers, through professional opinions and assessments.

When the VA stopped using detailed specifications, it also discontinued this three-element quality assurance program, believing that the program was based on using detailed specifications and was therefore no longer applicable. As a result of this change, however, quality standards were not consistently established in purchasing devices, and inspection programs were no longer dependable. Again, GAO found that stocked items were frequently poor or inappropriate. Surgical instruments had defects, such as cracks, pits, or rough edges, that could prevent sterilization. Some did not close properly or failed to meet VA test standards. Other items had missing or broken parts and misaligned components. Finally, when medical centers received these defective items, their complaints were often ignored.

In response to the GAO study, the VA reinstituted some of its traditional measures for quality assurance:

- reestablishing a qualified products list for surgical instruments,
- developing inspection criteria for depot items to supplement purchase descriptions, and
- transferring responsibility for quality complaints from the purchasing divisions to T&E to improve objectivity and responsiveness (as discussed at length in ch. 4).

The VA has now taken a further step through an interagency agreement with the Food and Drug Administration (FDA). As of March 1982 the FDA assumed certain quality assurance responsibilities for VA medical device contracts, including depot stock inspection and investigating the manufacturing practices of potential contractors (116).

There is still concern, however, that CIDs and purchase descriptions will contribute to the lower quality of VA medical equipment and supplies. Surgical instruments, for example, have drawn complaints from VA medical centers, and for the same defects (67,79).

The issue of quality has also arisen regarding hospital beds. VA testing and evaluation led to the recommendation that beds be purchased with specific safety controls for repositioning, and this recommendation was incorporated in earlier product specifications. VA marketing research also found that certain positioning features significantly increased cost, yet that VA hospitals rarely used these features. Neither of these findings, however, has been consistently applied in VA centralized purchasing contracts using CIDs. Instead, more expensive beds and beds with fewer safety features have often been purchased because of poor product descriptions (67,79).

Nevertheless, such problems do not demand a return to the old specifications. The VA, veterans' service organizations, and private manufacturers and vendors agree that device specifications were often too rigid, stifling innovation given the size of the VA market. One private firm made wooden canes considered obsolete by every other purchaser, yet it maintained a profitable operation for several years because of the VA's outdated specifications. Bradburd also found that VA specifications for medical equipment were often written by considering a particular manufacturer's product, putting other manufacturers at a serious disadvantage (14) (see app. C). Other VA specifications were simply unenforced given the range of suppliers (12,54,67).

The VA, then, has tried to strike a balance in using CIDs, writing device product descriptions both to maximize the number of potential suppliers and to prevent an influx of inferior items. Commodity managers, who are responsible for both contracts and developing CIDs, now work closely with T&E to incorporate device evaluations and market research into product descriptions (12).

However, despite the attempted cooperation of T&E and purchasing divisions, problems may still arise because their individual goals of quality and efficiency may conflict. Purchasing divisions are charged to contain VA costs as well as to see that supplies are available. Also, factors other than price and availability (e.g., product reliability and performance), while taken into account, are more difficult to quantify in purchasing.

### The VA's Impact on Product Cost

The impact of the VA's procurement system on product cost depends on supply conditions, the type of procurement (centralized or decentralized), and VA contract procedures and policies. Many industries believe that the VA and other Government agencies obtain the best buy (44). Becker and his colleagues found the "overriding premise" in selling to Government agencies is that they expect low prices. However, industries still can benefit (9):

> Government orders are sought by most manufacturers that would be unacceptable and unprofitable if normal accounting practices were followed. The manufacturer generally sells at these reduced prices based on the premise that this is "incremental" or add-on business. . . . With smaller margins than would otherwise be realized . . . the manufacturer may . . . increase manufacturing . . . utilization of otherwise unused production time and facilities.

The VAMKC decides to manage an item centrally based on several factors: usage, need, customer service, and cost.[9] Certain minimum criteria must additionally be met:

- $15,000 in potential sales for new items,
- an estimated savings of at least 15 percent for supplying an item through depot stock,
- annual sales of at least $10,000 to retain an item supplied through depot stock,
- the use of an item by at least 10 percent of all VA hospitals to retain an existing method of supply, and
- a realized savings of at least 5 percent on any centralized contract.

These criteria have probably contributed to efficiency and savings in VA centralized procurement.

There is also some empirical evidence that VAMKC policies result in lower product costs. A recent study by IMS America, Ltd., under contract to the VA, concluded that the VA is a "most favored customer," even compared to large institutional buyers (44). The study compared the prices of selected items for the VA and the Hospital Corp. of America, including catheter needles, syringes, surgical tape, surgical blades, and common pharmaceuticals. The study found that the VA consistently obtained the best buy and concluded that the results probably would have been the same had another sample of products been compared. "The size of the VA as a buyer alone clearly places the VA at an advantage," the report observed (44).

VA centralized procurement has also compared favorably with other Federal procurement. A recent survey of 25 hospitals in 10 States by the Inspector General of the Department of Health and Human Services found that the price of cardiac pacemakers was about 17 percent higher for Medicare than for the VA (120).

Two studies have criticized the VAMKC's management of the depot system. The 1982 GAO report and the 1983 President's Private Sector Survey on Cost Control found that VA inventory management techniques increased costs (34).[10] The VA is now simplifying and automating its ordering and storage systems.

OTA examined the likely effects of VA policies on the costs of procuring nine types of major medical equipment: X-ray equipment, computerized tomography (CT) scanners, digital imaging equipment, nuclear diagnostic equipment, nuclear magnetic resonance (NMR) and positron emission tomography (PET) scanners, ultrasound diagnostic equipment, patient monitoring equipment, electro-encephalogram (EEG) and electrocardiogram (ECG) equipment, and hemodialysis equipment (this study is presented in app. C). The study focused on how the VA affects and is affected by market conditions, and especially on how VA procurement policies affect the prices and products manufacturers offer to the VA. Five official contract procedures and one unofficial VA policy were examined for their effects on equipment costs: 1) brand name justification, 2) the firm fixed price clause, 3) public disclosure requirements, 4) no volume commitment, 5) the most favored customer clause, and 6) the unofficial reluctance to procure mixed equipment systems.

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[9] Once a decision has been made to procure an item centrally, contracts are developed through either a formal bid or negotiation, depending on need, demand, and number of manufacturers (12).

[10] The President's Private Sector Survey on Cost Control further recommended the complete dismantling of the VA depot system based on its own cost-accounting analysis. Analysis of this issue, however, is beyond the scope of this report.

Analysis of the likely effects of these policies indicated that they have different, perhaps conflicting results on procurement prices:

- *Brand Name Justification*.—When a VA hospital is authorized to buy equipment, the VAMKC forwards to the hospital a list of suppliers on contract whose equipment meets the requirements of the purchase order, ranked by order of cost. The hospital is required to buy from the least-cost supplier unless it can justify purchasing from a different source (e.g., because of service availability). This requirement is called brand name justification. Because suppliers are anxious to maintain their share of the VAMKC market, the requirement almost certainly results in lower prices.
- *Firm Fixed Price Clause*.—Under the terms of a VAMKC contract, suppliers cannot increase prices during the contract year. Furthermore, if they lower the price at any time during the year, the lower price holds for the remainder of the contract year. The firm fixed price clause may or may not result in lower procurement costs. Suppliers offer temporary price discounts in the private market to promote their products. Normally, promotional offers would probably be extended to the VAMKC as well, but because of the firm fixed price clause, suppliers are reluctant to make them. Even the requirement that prices not be increased during a contract year has indeterminate effects on procurement costs. Although the requirement does protect those who buy through the VAMKC from price increases, suppliers may charge a higher price at the start to ensure a profit. Altogether, it is extremely difficult to determine the net effect of the firm fixed price clause.
- *Public Disclosure Requirements*.—By law, the public has access to VAMKC procurement prices for medical equipment. Both theoretical and empirical evidence support the view that this results in higher procurement costs for the VAMKC. First, a firm's benefits from cutting its price are in part a function of the so-called retaliation lag, the length of time before rivals learn of the price cut and cut their own prices in response. Price disclosure requirements reduce the retaliation lag, and therefore discourage price cutting in the VAMKC market. Because other buyers of medical equipment also have access to the price data, the VAMKC price may serve as the other buyer's target in pricing negotiations, which can also inhibit price cutting in the VAMKC market. Suppliers of X-ray, nuclear medical, patient monitoring, and hemodialysis equipment have stated that prices offered to the VAMKC are higher because of the contract disclosure requirement. Some suppliers said the disclosure requirement did not affect pricing in their markets because pricing information was widely available from other sources.
- *No Volume Commitment*.—Having a contract with the VAMKC does not imply any contractual volume commitment in procurement. For most equipment categories (other than X-ray and nuclear diagnostic equipment), the absence of a volume commitment is a major factor in pricing. There are two likely reasons why volume commitment would be unimportant in some industries, but very important in others. First, when equipment is purchased from stock and is fairly standardized, a volume commitment can reduce manufacturing costs that can be passed on to the buyer, but not when the equipment is custom made. Second, the effects of volume commitment seem to depend on whether equipment is expensive or inexpensive. When equipment is inexpensive, the costs of preparing contracts and marketing

are higher relative to the purchase price of the equipment. In this situation, the cost savings that come with volume commitment are more significant. Some suppliers indicated that they might lower prices by 5 to 10 percent in exchange for a volume commitment. One supplier in the ultrasound market stated that a group purchase of even 15 to 20 units would suffice for a larger price discount than is now offered.

- *Most Favored Customer Clause*.—Under the terms of a VAMKC contract, suppliers are prohibited from selling their equipment under a "like contract" to any private buyer at a price lower than that offered the VAMKC. If a lower price is offered to a private buyer, this price must be given to the VAMKC for the rest of the contract year. This stipulation helps ensure that the VAMKC's clients benefit from vendor competition in the private market. Although the strictness with which the most favored customer clause is interpreted varies from one equipment category to the next, it almost certainly reduces VAMKC equipment procurement costs. The most favored customer clause can also have a powerful impact on private buyers. In a few markets, private buyers are offered lower prices than the VAMKC when they make contractual volume commitments, on the grounds that these are not "like contracts." The effect of the clause is obviously less in these markets. However, in cases of no volume commitment, the most favored customer clause may have the effect of increasing prices that private buyers must pay for medical equipment, especially for X-ray, nuclear diagnostic, ultrasound, patient monitoring equipment, and CT scanning devices.
- *Reluctance to Procure Mixed Systems*.—Although there is apparently no formal requirement to this effect, VAMKC personnel are reluctant in practice to purchase mixed medical equipment systems, those in which items of different companies are interconnected. The most important reason for this is the difficulty of assigning financial responsibility for repairs under warranty, in addition to that of determining responsibility for actually making the interconnection. Unfortunately, this VA policy may practically eliminate many smaller companies from the procurement process, causing higher initial procurement costs.

Perhaps the greatest effects on VA product costs are the result of its generally decentralized procurement. Many purchasing decisions are made by individual VA facilities, not by the VAMKC.

Two decades ago, VA medical centers needed to make few purchases on the open market, only 10 percent of their supplies. When the military draft ended, it was hard to keep physicians in the Armed Forces, partly because they could not obtain the medical instruments and supplies that they preferred. For this reason, VA and DOD hospital physicians were allowed to purchase more items through the open market (34), the purchasing arrangement that now accounts for $498 million, or 38 percent, of VA medical center supplies and equipment (table 5).

A 1980 GAO report on VA medical center purchasing analyzed the large proportion of open market purchases (100). GAO concluded that the VA was paying too much as a result of the following:

- The VA had not standardized many common items. Medical centers were therefore independently purchasing many different products for basic needs, which increased purchasing costs.
- The VA lacked sufficient visibility over medical center purchases to address central procurement issues effectively, and needed an improved information system.
- Medical centers failed to use the VA's "mandatory" supply sources, even though common items were available at lower cost from these sources.
- Competitive bids, although required by Federal procurement regulations for purchases above $500, were not often obtained, providing little assurance that reasonable prices were paid.
- Neighboring VA medical centers independently obtained common supplies, failing to share product and vendor information and purchasing and contracting experience.

The VA generally agreed with GAO's conclusions, and the Central Office tightened control over some aspects of local purchasing by instituting quarterly reports on medical centers' purchases from other than mandatory sources. Medical centers have complained, however, that their purchasing patterns have often stemmed from problems with the VAMKC, for example, the problems of product quality discussed earlier in this chapter. The VAMKC also delayed from 3 to 6 months in sending mandatory source listings to the medical centers, though apparently at least in part because of the change to a newly integrated system of Federal stock numbers.[11] Because of such delays, items may be centrally managed, but medical centers are unaware of it when ordering supplies and equipment. These delays also weakened the control sought by the Central Office in initiating quarterly reports (43,51).

In other areas, there has been little or no response to the 1980 GAO report. Neither the Central Office nor neighboring VA medical centers have further consolidated purchases or shared product or vendor information. Such coordination has been achieved by VA medical centers on occasion, but only rarely and by coincidence; for example, buyers from VA medical centers in Washington, DC, Baltimore, Maryland, Martinsburg, West Virginia, and Perry Point, Maryland, came together for a few years to buy plated media for clinical laboratories. One factor inhibiting consolidated buying is the relative lack of automated data management systems for supply officers at local medical centers, providing little opportunity to share contract and purchase experience (18,43,51).

More recently, the President's Private Sector Survey on Cost Control criticized the open market purchasing by VA medical centers, and called for more central purchasing to achieve the price advantages of buying standard items in quantity. The report commends the recent VA-DOD shared procurement efforts, but suggests that VA (and DOD) management provide more routine, detailed reports highlighting the number or value of items purchased on the open market locally that might be more economically purchased under nationally negotiated contracts. With better developed information systems for supply management and by "aggressively seeking out commonly purchased items to be included in contract negotiations," VA hospitals could expect to attain the following (34):

> . . . a level of local purchases that approximates the 15 to 25 percent rate experienced by private sector hospital management firms. This level should be given to local hospital personnel as a management objective. These personnel have performed well toward other goals and it is reasonable to believe that they can also achieve these goals. This method has worked well in the private sector hospital chains.

## DISCUSSION

With regard to marketing, purchasing, and supplying medical products, the VA has three general goals: product innovation, product quality, and low product cost. Individually, these goals have been accomplished in various ways. Ideally, they should also be attained together. At least with respect to commercially available devices, however, the VA's organization and decisionmaking have at times exacerbated the inherent tension among these goals.

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[11] The VA cataloging operations are centralized at the VA supply depot in Hines, Illinois. Data on items entering the supply system and on changes in existing items are submitted by medical centers and central procurement programs to the Cataloging Division to be cataloged in the Federal Catalog System. Cataloged data are then submitted to the Defense Logistics Services Center in Battle Creek, Michigan, for national stock number assignment. The national stock number identifies an item through all phases of logistics by all Federal agencies. A VA master computer file of all repetitively procured items contains the national stock numbers and relevant descriptive and management data for all supply transactions involving these items. User catalogs are produced and regularly updated for centrally and noncentrally managed items. Additionally, nonexpendable items are cataloged for property accountability. The major problem in cataloging is eliminating duplicate stock numbers for identical items. The VA-DOD Shared Procurement Program is coordinating the cataloging of all new medical items and reviewing those already cataloged to eliminate duplication. The VA also participates in the Federal Supply Management Council Working Group for Cataloging Systems in developing Government-wide cataloging policies and practices for improved supply management. On Nov. 1, 1982, the VA became the cataloging agent and manager for civil agencies of Federal Supply Group 65, Medical, Dental, and Veterinary Equipment and Supplies (121).

Available evidence indicates that the VA's centralized procurement programs, through various contract and distribution mechanisms, have often ensured low prices for their medical centers' equipment and supplies. Manufacturers also generally express a positive view toward the VAMKC process. The VA is perceived as "progressive" in its purchasing, and VA central procurement staff are generally viewed by device manufacturers as knowledgeable and fair (see app. C).

Nevertheless, the VA's procurement of medical equipment can be improved. For example, the VAMKC could consider making contractual volume commitments, in particular, for patient monitoring, EEG, ECG, hemodialysis, and ultrasound equipment. Even if the VA practice of decentralized purchasing continues for these types of equipment, enough VA hospitals may want a given supplier's product to warrant a volume commitment that would ensure a greater discount.

The VAMKC might also alter contract disclosure requirements so that contract price information is not accessible until 6 months after the beginning of a contract year. This policy would provide virtually all the protection of public disclosure requirements but could increase the willingness of manufacturers to discount their products.

Last, the VAMKC should explicitly recognize that the purchase price of major medical equipment often amounts to a small fraction of annual operating costs. Perhaps the major complaint of device manufacturers is that the VA considers purchase price only—not total operating costs—in determining its suppliers (see app. C for analysis).

Lower equipment and supply costs of course, must not be obtained by sacrificing product quality. The VA has implemented new quality assurance policies over the last few years, attempted to improve the objectivity and responsiveness of its quality complaint system, and established a special agreement with the FDA to obtain its expertise in quality assurance. Even so, there must be closer monitoring of the VA's use of specifications, purchase descriptions, and CIDs to ensure quality control.

The VA has adopted over 60 CIDs for medical supplies and expendables alone, and is in the process of adopting some 90 more (12). These documents have influenced the purchase of medical devices and will continue to.

Given its use of purchase descriptions and CIDs, the VA should consider the merits of comparative evaluations. These would more explicitly identify device alternatives for VA customers. Comparative evaluations could also identify, and perhaps evaluate, positive and negative features of the different devices. Product quality features (e.g., safety, durability, and performance) could then be considered along with cost in making choices about devices.

The potentially most useful comparative method now is cost-effectiveness analysis. In considering both economic and clinical information, this method integrates concerns about costs with those about quality. In a cost-effectiveness analysis, an outcome is specified (e.g., a patient's functional status) and the costs of alternative means to achieve it (e.g., using devices) are compared.[12]

Although cost-effectiveness analyses and similar analytic techniques have certain methodological weaknesses, they can still illuminate issues and synthesize relevant data. Comparative analyses are neither simple nor necessary for every type of device. Yet they can improve decisions and purchasing contracts, depending on the VA's use of them. More generally, integrating all the VA's information in purchasing seems as promising as it does challenging.

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[12] For more discussion on cost-effectiveness analysis, see U.S. Congress, Office of Technology Assessment, *The Implications of Cost-Effectiveness Analysis of Medical Technology*, GPO stock No. 052-003-0076 (Washington, DC: U.S. Government Printing Office, 1980) (107).

Increased procurement through centralized contracts would promote the VA's leverage in the market because the size of its market would grow. The large number of medical centers' open market purchases now reduces the VA's advantages as a large buyer. Among the possible benefits of the VA's being a larger buyer of medical supplies are at least two important ones: 1) greater price discounts, and 2) the encouragement of device innovation by providing a larger early market for new products (52,128).

## Chapter 6

# Adopting, Using, and Financing Devices

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# Adopting, Using, and Financing Devices

The desired result of all the activities directed toward medical devices is the appropriate adoption and use of these devices. In examining the capacity of the Veterans Administration (VA) to meet veterans' needs for such devices, it is thus necessary to look at the VA system of adopting and using devices, including selecting, providing, and paying for them. Issues of resource allocation must also be considered in examining this system.

Veterans adopt and use medical devices, depending primarily, though not entirely, on the VA programs and services for which veterans are eligible. Through these programs and services, veterans receive devices directly, have them financed, and learn about them (109).[1]

The VA makes available an enormous range of medical devices, including, for example, over 300 sensory aids for the blind (13). During fiscal year 1982, the VA provided over $81 million in prosthetic services. Each year it provides commercially available prosthetic devices and services to about 1 million disabled veterans (118). In addition, it provides a range of devices through routine patient care services.

Since adopting and using medical devices depends to a great degree both on veteran eligibility and VA budgeting and financing, these topics are discussed first. More specific policies and issues affecting adoption and use of devices—rehabilitative devices and medical equipment and supplies—are then examined. Finally, more explicit approaches that consider device adoption in light of resource allocation are addressed.

## VETERAN ELIGIBILITY FOR PROGRAMS AND SERVICES[2]

Many VA programs serve veterans' needs, including those for: 1) income maintenance, 2) medical care, 3) social services, 4) educational services, 5) vocational rehabilitation and independent living, and 6) housing assistance. VA programs vary not only in purpose, but in origin, eligibility criteria, and ways of providing services (e.g., through funding only, funding and referral to services, or direct provision of services), and in financing and administration.

The greatest expenditures for medical devices are made through income maintenance and related transfer payments and medical care programs.

### Income Maintenance

The VA administers a major income maintenance program through compensation for service-connected disabilities and pensions for non-service-connected disabilities. The VA estimated that in fiscal year 1983, an estimated $10.2 billion would be spent for 2.6 million veterans through the compensation program, and $4.0 billion for 1.8 million veterans through the pension program.

The amount veterans are compensated for service-connected disabilities depends on how much their disabilities affect their earning capacity in civilian occupations. Additional compensation is provided for dependents. To be eligible, a veteran must have contracted a disease, suffered a nonmisconduct injury, or aggravated an existing disease or injury in the line of duty, during war or peacetime. Proof of disability is based on service medical records. Service connection may be granted by presumption if a veteran develops one of several chronic diseases within 1 year of discharge from service, tuberculosis or Hansen's disease within 3 years, or multiple sclerosis within 7 years. Once service connection is established, the VA assigns a percentage to the disability from an established "Schedule for Rating Disabilities" (111). Eligibility is thus based on medical criteria and proof of service. Vocational factors were considered only in developing the "Schedule for Rating Disabilities." An individual does not have to prove the inability to earn an income or to support himself or herself with unearned income.

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[1] The issue of eligibility becomes particularly important since, according to VA estimates, 58 percent of VA patients are at or below the poverty line. Data compiled by the National Center for Health Statistics from 1971 to 1974 show that the lower a hospitalized veteran's income, the more likely he is to be treated in a VA rather than non-VA hospital. In 1980 the VA estimated that veterans discharged from VA hospitals were five times more likely to have annual incomes under $4,000 (26 percent) than over $10,000 (5 percent) (96).

[2] Except as noted, this discussion is based on an earlier OTA report *Technology and Handicapped People* (109).

Pensions for non-service-connected disabilities provide incomes to totally and permanently disabled veterans and their dependents whose income is below an established standard. To be eligible, veterans must have served at least 90 days, including at least 1 day of wartime, must be medically determined to be disabled, and must have personal resources and income below a legislated amount. At age 65, veterans are considered disabled regardless of their physical condition or income. Disabled survivors of veterans may also receive benefits if they meet the income test (95). Eligible veterans receive VA cash payments (with the amount determined by statute), medical and social services, and housing and education benefits.

Erlanger and colleagues note that although the distinction between service- and non-service-connected disabilities has always been made in discussing veterans' benefits, the legitimacy of all veterans' pressure for benefits has never been seriously questioned, as was observed in the 1980 hearings on the Veterans' Disability Compensation and Survivors' Benefits Amendments (111). Veterans' disability programs have always been separate from civilian programs, with better benefits and less strict eligibility requirements. The major concern of policymakers has been the cost of providing all eligible disabled veterans with all necessary services (26).

Income maintenance programs are important for disabled veterans not only for income, but also for supplemental benefits and referrals to other services. Both device and service technologies are provided under supplemental benefits, while the income itself allows recipients to purchase devices not covered by supplemental benefits. Income maintenance from both compensation and pension programs are funded from general revenues.

## Health and Medical Care

Chapter 2 described the VA's comprehensive medical and rehabilitative services for veterans with service-connected disabilities and for those with non-service-connected disabilities unable to pay for medical care. These services are federally funded. Priority for medical and rehabilitative care is given to veterans with service-connected disabilities, an estimated 3 million people. Veterans with non-service-connected disabilities may be admitted to VA hospitals if they are unable to pay for hospital care elsewhere and if beds are available.[3] Approximately 80 percent of VA patients are veterans without service-connected disabilities (114).

VA health and medical benefits include prehospitalization, hospitalization and posthospitalization care, prosthetic and medical devices, nursing home and domiciliary care, devices, transportation services, outpatient services, and prescribed drugs. Unlike coverage under Medicare and Medicaid, all technologies and devices suited to an eligible veteran's circumstances and needs are made available. The VA provides blind veterans with necessary services and devices to overcome their handicap and provides other disabled veterans with technologies and devices deemed medically necessary. A growing concern of VA users and policymakers is the cost of covering all available technologies and devices. There are now funding restrictions for some medical care for veterans without service-connected disabilities; for example, a foster home program is available to such veterans only when they can pay its cost (109).

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[3] The "inability to pay" requirement does not apply to veterans: 1) 65 or older, 2) receiving VA pensions, 3) eligible for Medicaid, 4) rated service-connected disabled, or 5) considered former prisoners of war. It also does not apply to those requesting medical services in connection with exposure to dioxin or other toxic substances in herbicides or defoliants (e.g., Agent Orange) used for military purposes in Vietnam Aug. 5, 1964, through May 7, 1975, in connection with exposure to ionizing radiation from detonated nuclear devices as a result of participation in the testing of such a device, or in the U.S. occupation of Hiroshima and Nagasaki between Sept. 11, 1945, and July 1, 1946 (96).

# VA FINANCING AND RESOURCE ALLOCATION

Table 6 shows outlays for veterans' benefits and services by functional categories for fiscal years 1981 through 1983. Approximately 70 percent of the VA budget represents entitlement programs, such as the pension and compensation programs. Spending for these programs is "uncontrollable" in that Congress must modify existing law by changing the eligibility criteria in order to affect spending. The remaining 30 percent of the VA budget goes to discretionary programs, primarily medical care. Spending for discretionary programs can generally be changed through the appropriations process (96).

Veterans who seek VA medical care, then, are served within the limits of VA resources and legislated priorities (94). Under a limited and controlled budget, the VA health care system plans for 1 and 5 years ahead. Alternative plans are prepared, ranging from a 5 percent cut in the present budget to an increase in real terms. Once Congress fixes the appropriation, the budget is then set for the following fiscal year. A reduced appropriation, of course, requires a corresponding reduction in staff or services.

Once its appropriation is set, the VA health care system is characterized by highly decentralized planning and financial management. The VA has regional and functional health care market areas and has assigned fiscal and budgetary authority to the regional consortia of its medical centers.

**Table 6.—Outlays for Veterans' Benefits and Services, Fiscal Years 1981-83**

| Items | Outlays by fiscal year (millions of dollars) 1981 (actual) | 1982 (estimated) | 1983 (estimated) |
|---|---|---|---|
| Income security | $12,909 | $14,070 | $14,843 |
| Education, training, and rehabilitation | 2,254 | 1,883 | 1,557 |
| Hospital and medical care | 6,965 | 7,594 | 8,108 |
| Housing | 201 | −68 | −863 |
| Other benefits and services | 662 | 680 | 741 |
| Offsetting receipts | −3 | −3 | −3 |
| Total outlays | $22,988 | $24,155 | $24,383 |

SOURCE: Budget of the United States Government for Fiscal Year 1983, pp. 5-166, as reported by U.S. Congress, Congressional Research Service, *Medical Care Programs of the Veterans Administration*, Report No. 83-99 EPW (Washington, DC, May 16, 1983).

Regional allocations are prospectively budgeted by the Central Office. There are now 28 subdivisions known as "Veterans Administration Medical Districts" (fig. 6). Each medical district typically represents 4 to 10 VA medical centers that all offer primary and secondary care and some access to tertiary care. This "regionalization" in medical district budgeting is intended to help coordinate services provided by all members of the district, to avoid unnecessary duplication and to encourage new services only where they are required by large populations (16).

The formula used in resource allocation gives some weight to outpatient visits but more to bed occupancy. A new system for budgeting inpatient care based on diagnosis-related groups (DRGs) is being introduced (see the corresponding section below). In the future, the formula may be changed to reflect the size of the veteran population, adjusted for age (29,59).

## Management Initiatives

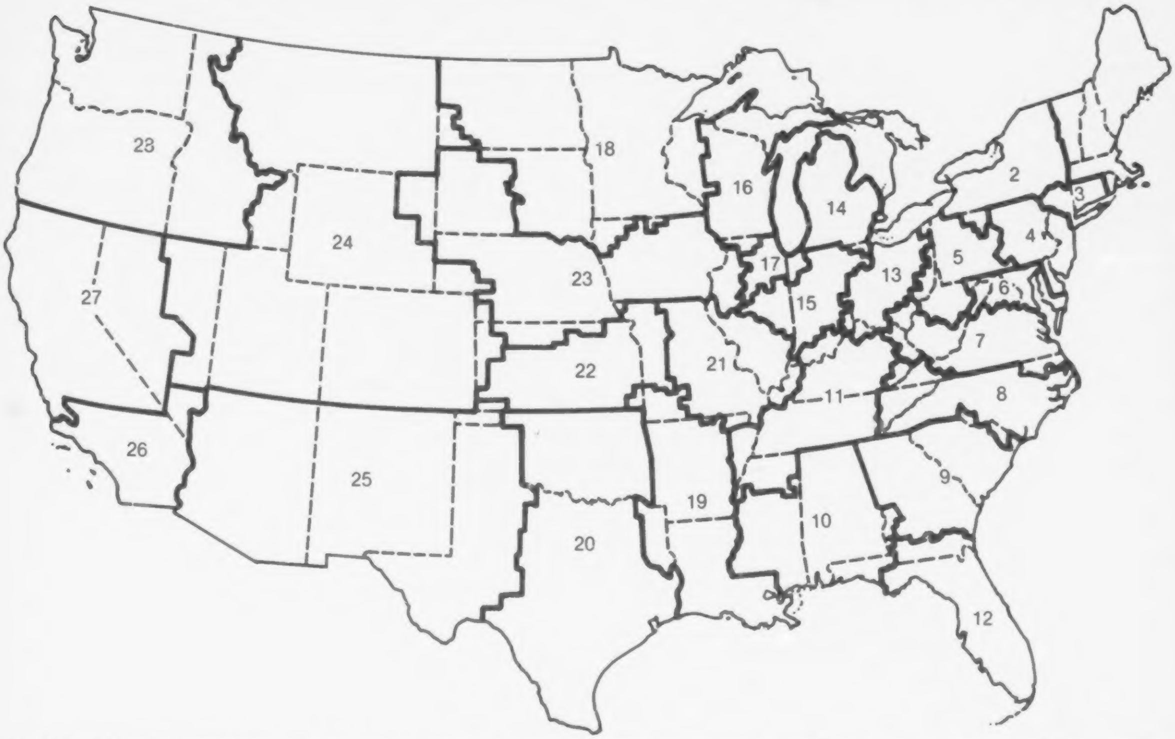
Several health care management initiatives have been taken in recent years through both legislative mandate and administrative fiat. These initiatives affect the VA's allocation of resources and adoption and use of devices, particularly equipment.

### Facility Planning

Each VA medical center annually prepares a construction and facility improvement plan covering the next 5 years. This plan, which is reviewed and approved by the Central Office, proposes construction according to program and service plans.

Each year, the VA develops and submits to Congress a 5-year comprehensive medical facility construction plan for VA projects requiring over $2 million. The plan submitted in June 1982, covering fiscal years 1983 through 1987, identified 252 projects with a total estimated cost of $5.4 billion (119).

Figure 6.—Veterans Administration, Department of Medicine and Surgery Medical Districts, 1983



SOURCE: U.S. Veterans Administration, as reprinted in U.S. Congress, Congressional Budget Office, Human Resources and Community Development Division, *Veterans Administration Health Care: Planning for 1990* (Washington, DC, February 1983).

Construction needs for projects costing less than $2 million are also identified from the medical center facility plans. For fiscal years 1983 through 1987, such projects numbered more than 1,400, with an estimated total cost of $850.4 million. In fiscal year 1982 the VA began emphasizing these smaller projects and proposed an increase for its fiscal year 1983 budget for this purpose (119).

### Medical Equipment Reporting System

Not surprisingly, the VA's medical equipment inventory has increased in both quantity and complexity over the years. To manage all this medical equipment, the VA has developed an interactive computer-based Medical Equipment Reporting System to help both VA medical centers and the Central Office maintain and access equipment histories, identify important performance trends, track mandated corrective actions, and establish a data base for utilization review and resource planning. Each VA medical center will eventually have access to both local and systemwide experiences and trends (119).

### Health Resources Sharing

Public Law 97-174, the VA-Department of Defense Health Resources Sharing and Emergency Operations Act, was intended to promote cost savings while providing veterans and the military more comprehensive services. The two agencies plan several joint efforts (121):

- Establishing a VA-Department of Defense Health Care Resources Sharing Committee to review policies and practices and to recommend changes. Monitoring the acquisition of major equipment and the locations of new facilities will be part of the committee's responsibilities.

- Publishing guidelines based on the committee's recommendations, which must not adversely affect the range of services, quality of care, or established priorities of either agency.
- Authorizing interagency sharing agreements among all medical facilities for referrals, with reimbursement to the facility delivering care.

The VA is first determining services that can be shared, to permit direct reimbursement. Sharing will primarily be locally initiated, but a few programs will be developed in the VA's Central Office and the Pentagon.

The VA's authority to share specialized medical resources was first established in 1966 (in Public Law 89-785) to permit VA medical centers to share underutilized, specialized, scarce, and costly resources with other medical centers, community hospitals, Federal and State hospitals, clinics, and blood and organ banks, so as to eliminate duplication. The law similarly permits the VA to use community resources for veterans. Shared resources have included computed tomography (CT) scanners, electron microscopy studies, specialized laboratory procedures, nuclear medicine services, radiation therapy, cardiac catheterization, open heart surgery, dialysis, ultrasound, and mammography (119).

### Medical District Initiated Program Planning

Perhaps the VA's most important step for the adoption and use of devices has been Medical District Initiated Program Planning (MEDIPP), begun in 1981. MEDIPP is a long-range "strategic planning system" giving greater responsibility for resource allocation to the VA's 28 medical districts (136).

MEDIPP evolved to respond to two seemingly incompatible conditions: the short-range demand for more (and different) services and long-range declining demand, both a function of the aging veteran population. As the many veterans of World War II and the Korean conflict enter their 60s and 70s, their health care needs will increase. Yet, as these veterans die, the demand for services will drop sharply, especially if no major military conflict brings large numbers of veterans into the system (123).

From 1970 through 1979 VA medical care appropriations tripled, from roughly $1.7 billion to $5.3 billion. Cost consciousness increased correspondingly toward the end of the decade. Since 1977 the VA has faced stable or declining health care budgets (adjusted for inflation). Given the general political concern about VA spending and the changing demographics of the veteran population, the VA has recognized that past planning and management approaches are no longer feasible. MEDIPP is intended to provide the basis for planning and managing the VA's changing health care delivery needs (59,123).

Since the VA will certainly have to discontinue some services or facilities, organizational and constituency understanding and acceptance may be significant hurdles for MEDIPP's success. For this reason, MEDIPP will involve administrative and clinical personnel at several levels within the VA Department of Medicine and Surgery.

MEDIPP begins its work each year on November 1 when the VA's Chief Medical Director publishes a list of the general issues, objectives, and goals for the immediate and long-range future of the Department of Medicine and Surgery programs. This report is used by each VA medical district, which appoints a district planning board and staff to develop a district plan. District plans reflect demographic analysis, a workload forecast, and a review of local resources submitted by the VA facilities within its jurisdiction. District plans are reviewed by district and regional administrators and councils, and when approved, submitted to the VA Central Office (119,136).

In MEDIPP's first year, 28 medical district plans were submitted to the Central Office on November 1, 1982, covering fiscal years 1985 through 1990. More than 400 administrative and clinical personnel helped prepare the plans, along with the representatives from veterans' service organizations who served on medical district planning boards, advisory committees, and task forces. These initial district plans will provide the basis for developing a national strategy that identifies program directions of the Department of Medicine and Surgery, trends in veterans' health care needs, and the types and sizes of facilities and mix of health care services required to meet these needs (119).

An initial problem in MEDIPP has been developing adequate program standards and criteria toward formulating VA district plans and national policies. Like health planning laws and programs (e.g., certificate-of-need requirements) that regulate private health care investments, MEDIPP must set quantitative and other standards for specific technologies, such as general hospital beds, open heart surgery, cardiac catheterization, and end-stage renal disease services. The VA is also now developing case-mix workload and general staffing guidelines for new planning standards (7,59).

The promise of MEDIPP is in providing the VA an initial framework for rational planning in an era of dwindling health care resources. Its significance in relation to devices mostly concerns equipment. District plans will propose the creation, expansion, or dismantling of services, specifying requirements for construction, staffing, and new equipment. The implications of the plans for medical supplies will probably be vague. Likewise, changes in the adoption and use of prosthetic devices will be identified through MEDIPP only in the case of new rehabilitative services. However, MEDIPP could identify and monitor the need and demand for various types of major medical equipment. MEDIPP could then be used not only in planning, but also to track the adoption and use of major equipment. Requests and proposals for device equipment could then be considered in light of their cost effectiveness in delivering care. To some extent, VA-initiated research has already begun to explore these possibilities, as discussed below.

### Diagnosis-Related Groups

Another new process that may affect medical device adoption and use is setting VA inpatient budgets using DRGs (28). Although the VA has budgeted prospectively because of the congressional appropriations process, the use of a case-mix measure such as DRGs is intended to distribute funds more rationally among medical centers than have previous arrangements. DRGs classify patients by principal diagnosis, surgical procedure, age, presence or absence of significant comorbidities or complications, and other relevant criteria. The new Medicare prospective payment system for hospitals is also based on DRGs. The VA budgeting system and the Medicare payment system use similar mathematical models to assign patients to DRGs and to allocate resources among DRGs.

Data sources for the VA system include all VA discharge abstracts, costs by different service categories (medical, surgical, psychiatric), the current model of 470 DRGs used by Medicare, and the New Jersey Reimbursement Schedule. Since the VA has no patient-based method of assigning costs, the VA used New Jersey cost data to assign relative DRG weights to the VA discharges, and these weights were used for allocation decisions (27).

DRGs will also be used in VA utilization review and quality assurance programs (27). Capital purchases are excluded from the DRG rate, and hospitals do not keep surpluses. Thus, DRG budgeting will affect the use of devices more than their purchase, which will be affected more by MEDIPP.

## ADOPTION AND USE OF DEVICES

Eligibility and payment for services obviously affect the adoption and use of devices. The decision of whether to include a device in a specific service or to provide a device to an individual in delivering care is also assumed to have a major influence on adoption and use.

Individuals' circumstances and needs have traditionally been identified at the clinical level, within the relationship of patient and provider. VA medical, surgical, and rehabilitative services have been relied on to determine need, develop rationales for specific devices, and request procurement formally through the VA Office of Procurement and Supply (13).

### Rehabilitative Devices

After World War II, VA rehabilitation services were concerned primarily with treating a fairly large group of young war-injured veterans. The VA's rigorous pursuit of this mission, according to a 1977 National Academy of Sciences (NAS) report, led to its world leadership in the clinical use of devices and techniques for aiding physically handicapped people (62).

Today more than 80 percent of those treated through the VA's rehabilitative services have nonservice-connected disabilities, with many suffering from the chronic diseases associated with aging. The postwar period has also seen rapid growth in medical knowledge and technology, including substantial changes in treatment approaches in rehabilitation (62).

The VA provides rehabilitative devices through a number of special services and programs.

### Rehabilitation Medicine

All VA hospitals have rehabilitation medicine services, but only 52 have rehabilitation medicine bed sections. The VA rehabilitation programs vary in size, type, and organizational arrangement (62,119). For example, there is a cardiopulmonary rehabilitation program at the VA medical center in Wood, Wisconsin, and driver training programs for the handicapped at several other medical centers. In fiscal year 1982, the VA began using an additional teaching vehicle (the MED-VAN Mark IX system) for severely disabled veterans, such as quadraplegics, at two VA medical centers. Six independent living centers were established in 1981 at VA medical centers to eliminate the barriers that limit veterans in community living, including barriers that are physical, psychological, social, and environmental. More than 25 VA medical centers are also involved in rehabilitation programs focusing on the aging veteran (119).

### Spinal Cord Injury Centers

There are now 19 VA Spinal Cord Injury Centers across the country. They provide initial care, rehabilitation, and long-term care for about 7,200 patients. In addition, there are about 31,000 yearly outpatient visits of those with spinal cord injuries. Home care programs for these patients recorded 14,600 visits in fiscal year 1982. Many special services must be provided to the spinal-cord-injured patient, from medical and rehabilitation care to adjustment counseling. Urodynamic laboratories have been established recently for Spinal Cord Injury Centers to provide intensive rehabilitation and sustaining care. Urodynamic laboratories are essential for evaluating the neurogenic bladder, and proper diagnosis often permits patients to be catheter-free and avoid urinary tract infections (119,145).

### Blind Rehabilitation

In the Blind Rehabilitation Program, services are provided by the six VA Blind Rehabilitation Centers and Clinics, and by 75 Visual Impairment Service Teams located at VA medical centers.

The Blind Rehabilitation Centers give training in orientation and mobility, communication, manual skills, and activities of daily living, along with evaluating vision and prescribing aids such as electronic reading and travel aids. The Blind Rehabilitation Centers also provide counseling to patients and their families, physical reconditioning, and recreation, and they conduct research on blindness and rehabilitation, prosthetics, and sensory aids for blind people.

The Visual Impairment Service Teams focus on outpatient treatment, annually reviewing the health profiles, living circumstances, social adjustment, and personal needs of blind people. These teams include staff physicians, social workers, and other VA medical center personnel.

The VA also has a Vision Impairment Center to Optimize Remaining Sight. Currently there is only one such center, at the VA medical center in Kansas City, Missouri, under the Hospital Optometry Section of the Eye Clinic (141).

### Audiology and Speech Pathology

During fiscal year 1982, the VA issued approximately 34,000 hearing aids to eligible veterans throughout the Nation. The procedure for obtaining a hearing aid from the VA is straightforward. The eligible veteran applies for a hearing aid at the nearest VA facility, and is given otological and audiological examinations. During 1982 more than 574,000 patient visits were reported by the 98 VA audiology and speech pathology programs. Additionally, a program offering services by computer is being pilot tested in the southeastern region of the country (119,127).

### Prosthetics

By regulation, the prosthetic shops ("Orthotic Laboratories") of VA hospitals may make only temporary prostheses. Definitive prostheses must be obtained from commercial vendors under contract to the VA.

Definitive prostheses are obtained through a prosthetics representative, a veteran with a service-connected disability who is the purchasing agent for all prostheses, from eyeglasses to motorized wheelchairs. The 96 prosthetics representatives at some 80 VA facilities dispense more than $84 million per year in devices in initial and repeat prescriptions (62). Table 7 gives a sample of rehabilitative devices distributed to veterans in fiscal year 1982.

Clearly, the prosthetics representative is central in the adoption process. Representatives must be thoroughly familiar with all VA-authorized prosthetic, orthotic, and sensory aid devices, and other rehabilitative equipment. Representatives must also know fitting techniques, eligibility requirements, and device sources. They are responsible for educating the clinical and management staff at their hospitals about the prosthetics program. Finally, they must submit administrative reports and work with contracting prosthetics suppliers (159).

Prosthetics representatives serve as counselors for veterans who need prostheses. Clinic teams of physicians, physical or occupational therapists, prosthetists, and prosthetics representatives meet with the veteran to decide which, if any, prosthesis should be prescribed. They choose from among the devices approved by the Prosthetic and Sensory Aids Service (PSAS) of the VA. PSAS makes its decisions through its Prosthetic Technology Evaluation Committee on the basis of evaluative research conducted by the VA or other investigators. In some cases, clinic staff may recommend a prosthesis that has not yet been evaluated. PSAS is asked to rule on these cases individually (88). When it determines that new commercially available devices are needed, PSAS will formulate the technical specifications for the devices, and negotiate service contracts with private manufacturers directly or through professional associations, such as the American Orthotics and Prosthetics Association (13,24).

**Table 7.—Sample Rehabilitative Devices Distributed to Veterans, Fiscal Year 1982**

| Item | Number of devices | Value (dollars) |
|---|---|---|
| Aids for the blind . . . | 15,158 | $ 512,352 |
| Artificial limbs . . . . . | 10,598 | 10,171,840 |
| Braces . . . . . . . . . . . . | 36,306 | 2,336,293 |
| Corset belts . . . . . . . | 20,641 | 236,884 |
| Eyeglasses . . . . . . . . | 101,286 | 3,419,484 |
| Hearing aids . . . . . . . | 32,252 | 243,625 |
| Shoes . . . . . . . . . . . . . | 29,597 | 704,740 |
| Wheelchairs . . . . . . . | 30,981 | 10,055,721 |

SOURCE: U.S. Veterans Administration, *VA Annual Report 1982* (Washington, DC, 1983).

PSAS also directs the national VA prosthetics program, including the VA Prosthetics Center (see chs. 3 and 4); 20 Prosthetic Treatment Centers, which provide specialized services for a region; 53 Orthotic Laboratories, which fabricate and fit temporary limbs; 11 Restoration Clinics, concerned with artificial eyes, facial and body restorations, cosmetic hands, plastic ear inserts, and similar items; and prosthetic activities within VA medical centers and outpatient clinics (143).

### Past Problems

Prosthetics representatives specifically and the VA prosthetics program generally have been the focus of criticisms over the last several years. The 1977 NAS study of the VA concluded that the VA took much longer to obtain prosthetic devices than did private hospitals. In addition, the study questioned the prosthetics representatives' refilling device prescriptions that did not require a medical recertification of need (62). A 1979 VA program evaluation concurred with the NAS report, concluding that some prosthetic services for patients were too slow, and also noted that the program's efficiency and effectiveness were diminished by other factors (143). One was the reduction in the Central Office staff for PSAS from eight in 1973 to four in 1979. The report stated: "Liberalizing legislation has had the effect of increasing Prosthetic and Sensory Aid workload, yet program staffing was decreased. . . .Present staffing of the service would appear inadequate." To minimize increased workload and decreased staffing, various VA Central Office functions were assigned to selected field facilities. In several cases, no authority was delegated and no official transfer documents addressed these significant operating changes (2,143). The VA report further found no evidence of major program planning in the PSAS Central Office.

The NAS evaluation also concluded that the VA chain of command, in which prosthetics field personnel report directly to hospital directors, resulted in lack of direction to prosthetics representatives in the field (62):

> There is a lack of sufficient communication between VA Central Office program officials and [VA medical center] prosthetic representatives. Most problems in this area are due to a lack of upward communications. Upward communications must pass through [VA medical center] Operations to get to Prosthetic and Sensory Aids Service.

### Recent Policy Changes

Since the VA's internal evaluation of PSAS, the latter's Central Office staff was increased from four to eight persons and began to address some of the problems of the prosthetics program. To speed prosthetics procurement, for example, VA medical centers have been allowed since 1981 to directly purchase (through decentralized contracts) new, commercially available prosthetic or orthotic appliances and repairs for other prosthetic appliances costing up to $300 (2,118). Other efforts begun in 1982 were comprehensive training programs for new prosthetics representatives and other prosthetics personnel, revised contracting procedures for artificial limbs, a more systematic evaluation program (see ch. 4), a newsletter, and revisions of outdated training and specification manuals, many dating to the 1950s. In addition, the VA is now discussing reorganization that would put Rehabilitation R&D, PSAS, and the VA Prosthetics Center in one administrative structure (13).

Veterans' groups, such as Disabled American Veterans and Paralyzed Veterans of America, have supported recent PSAS policy changes, but feel many more are needed (2,39). Because of PSAS's very large field staff, veterans' groups are concerned that Central Office policy changes will be delayed (159). (App. B further discusses the concerns of veterans' organizations.) There are still many reports of disabled veterans' being provided inappropriate devices, because of either the practices of prosthetics representatives or Central Office policies. For example, wheelchairs procured by VA medical centers for hospital transportation are often distributed to veterans as prescription chairs. Such chairs have often not met veterans' needs and have not proved durable outside hospitals.

### Future Issues

Perhaps the major PSAS issue that the VA must address over the next few years is the prosthetics budget and related fiscal practices. The PSAS budget has tripled in 8 years to $84 million and has been projected to reach $500 million annually in 4 to 5 years (24). One reason for the steep rise in costs has been the increased purchase of sophisticated technology for handicapped people. Another reason is the increasing population of veterans whose mobility and senses are affected by aging (119). Probably the most significant force behind the escalation, however, is that providing prosthetics to veterans is unlimited by law (38 U.S.C. sec. 5023):

> The Administrator may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in other such manner as the Administrator may determine to be proper, without regard to any other provisions of the law.

Because the prosthetics budget receives no separate congressional appropriation, funds for prosthetics are drawn from the VA's annual appropriation for medical care, which is fixed prospectively. As a result, the prosthetics budget has drained resources from other parts of the health care budget as prosthetics costs have expanded.

The unconstrained prosthetics budget has also contributed to undesirable administrative practices within the VA. Because PSAS handles a high volume of devices, and because of the general availability of prosthetic devices, other VA rehabilitative services (Blind Rehabilitation, Spinal

Cord Injury Centers, etc.) have come to use PSAS as a purchasing clearinghouse for their own supplies and devices. PSAS therefore orders such supplies as pacemakers and kidney dialysis machines, which have very little to do with the functions of prosthetics representatives. Although this handling of supply functions has helped hold down the personnel requirements of other rehabilitative services, it has of course placed fiscal and administrative burdens on PSAS (24,160).

The VA has tried to constrain prosthetics costs through somewhat paradoxical fiscal practices. Although PSAS directs national VA prosthetics policies, it has little control or advisory function over the program's budget outside the Central Office. PSAS participates in the Central Office's initial distribution of funding to medical districts. The distribution of funds within the medical districts, however, is the responsibility of the medical district directors, and that within medical centers is the responsibility of the medical center directors. All medical districts and medical centers are semiautonomous, so that prosthetics services receive whatever budget allotment their medical center director determines. Poor communication between the PSAS Central Office and prosthetics representatives about budget needs has sometimes resulted from the separation of program and budget lines of authority (143). The proposed administrative realignment mentioned earlier should ameliorate this situation.

VA policymakers are examining several ways to resolve the increasing budgetary and fiscal problems in providing prosthetic devices. One approach is to have Congress appropriate a prosthetics budget separate from other health care funding. A second would limit devices to veterans with service-connected disabilities, now a minority of the disabled veterans served by the VA. A third approach is to assess more thoroughly the impact of the range of rehabilitative devices on the health and well-being of the individual veteran and on VA costs. The third approach would allow the VA to plan resource allocations more rationally. The VA has already implemented this approach to some extent through the Prosthetics Technology Evaluation Committee, as discussed in chapter 4. This committee makes decisions about rehabilitative device adoption and use in the context of general VA health care goals. Similar approaches can be taken in acquiring and using other devices, as discussed below.

## Medical Equipment and Supplies

Although the VA centrally plans its general policy, daily planning, administration, and delivery of health care is carried out by VA medical facilities. The VA Service Directors in the Central Office issue performance guidelines and routinely monitor the utilization and quality of all program units, but have very little authority over medical centers' decisions about device adoption and use. As noted above, budgets are allocated regionally, and medical equipment and supplies are purchased by local supply officers. The VA provides its central Testing and Evaluation Staff, but its role is advisory. The main Central Office influence over routine device purchase and use is through establishing testing standards, evaluating and centralizing contracting in light of those standards, and establishing purchasing source priorities for VA facilities. The determining factors for many device purchases are found within individual VA health care facilities (38,62). Physician freedom in choosing medical devices, for example, has been at least an implicit VA policy since the early 1960s.

### Controlled Item Acquisition

A clear exception to this purchasing pattern exists with equipment and supplies that the VA Central Office regulates as "controlled items." The controlled medical device items (listed in table 8) are generally relatively costly equipment, requiring an initial investment of $5,000 or more. They may also require substantial outlays for facility space, staffing, disposables, and maintenance (157). Controlled item acquisition can be regarded as analogous to certificate-of-need requirements (84).

Acquisition of medical and dental equipment on the VA's controlled item list may be initiated either locally or through a Service Director in the Central Office. In the first case, VA medical facilities often rely on Major Medical Equipment Committees, a cross-section of medical center staff and clinicians, to determine medical need. When it is warranted, the committee will request that

**Table 8.—VA Controlled Item List for Medical and Dental Equipment, 1982**

| Equipment type | Cost threshold (dollars) |
|---|---|
| Cardiac defibrillation | $ 4,500 |
| Physiological monitoring[a] | (b) |
| Clinical laboratory equipment and instrumentation | 30,000[c] |
| Electroencephalograph | 7,500 |
| Gastric hypothermia | 10,000 |
| Electron microscope for use in clinical laboratory | (b) |
| X-ray apparatus | (b) |
| Nuclear medicine | 5,000[d] |
| Ultrasonic unit, diagnostic | 5,000 |
| X-ray film processor, automatic or manual[e] | (b) |
| Dental cabinet, modular or unitized[e] | 1,200 |
| Dental operating chair[e] | (b) |
| Dental operating unit[e] | (b) |
| High velocity oral evacuation unit[e] | (b) |
| Dental operating light[e] | (b) |
| Automatic dental X-ray film processor[e] | 1,000 |
| Dental X-ray apparatus[e] | 2,500 |
| Acupuncture equipment and needles[e f] | (b) |
| Neurosurgical subcutaneous stimulator[e] | (b) |
| Surgical laser, including accessories[e] | (b) |
| Cardiac pacemaker surveillance equipment[e] | (b) |

NOTE: If a device's purchase price exceeds the "cost threshold," the purchase must be specially reviewed.

[a] Constant display of electrocardiographic curve, temperature, respiration, and blood pressure.

[b] No cost threshold.

[c] Per item or where combined cost components total $30,000 or more.

[d] Per item or items costing this amount in a single purchase.

[e] Except when acquired from a VA supply depot, a VA decentralized schedule, the VA Marketing Center, or a Federal Supply Schedule contract.

[f] Restricted to research in the Surgical Service.

SOURCE: U.S. Veterans Administration, *VA Manual*, subchapter E, change 155 (Washington, DC, Oct. 14, 1982).

an additional evaluation be performed on site in the medical center. Evaluations may also be conducted in conjunction with the VA's Medical Research Service, as was the case for CT scanners. The committees generally meet as needed to consider equipment standards and safety, to resolve problems involved in acquisition and use, and to develop and recommend policy (140).

Service Directors in the Central Office approve or disapprove controlled item acquisitions based on more or less explicit criteria of program needs, experimental or commercial status, and the support provided to other VA facilities and districts. Often, specific standards of productivity or utilization are developed in advance and disseminated to medical facilities.

Service Directors also seek to ensure that resources are available for planned or authorized program growth. If funding is not available through a facilities budget allotment, equipment may be reimbursed through a special fund maintained by the Chief Medical Director's office. This fund is used to allocate moneys, as they become available during the year, toward unfunded VA needs, although no explicit criteria are used in making these supplemental allocations (62).

When device acquisition has been part of a broader effort to initiate so-called specialized medical services (e.g., renal transplantation or open heart surgery), the VA's Chief Medical Director has in the past also established ad hoc advisory groups. These groups have been composed of VA and non-VA physicians with expertise in the particular program specialties, who, through regular meetings, and sometimes site visits, provide quality overviews of the programs.

For example, the shift toward purchasing CT scanners, rather than contracting for CT services, was justified in a 1978 VA report by the Special Central Office Advisory Group for Computerized Tomography Units (155). The report found that the cost of performing a CT examination on VA-owned scanners was only about 60 percent of the cost of the same examination obtained under contract from a civilian institution, which led to the VA's policy of purchasing CT equipment whenever possible (108).

## Social and Political Forces

As this chapter has shown, the VA has often developed well-defined procedures, conducted analyses, and presented technical criteria for equipment acquisition within its facilities. However, these facts should not obscure the political and social factors in VA device adoption and use. Regardless of the VA's planning, medical school preferences and politics have considerably influenced the VA system.

Thompson, for example, has argued that the VA's desire to be associated with medical schools has shaped hospital construction decisions far more than other concerns, such as promoting veterans' access to medical care (91). To ensure the quality of their personnel and foster medical professionalism, VA administrators have wished to locate facilities near medical schools and have sought to make their institutions hospitable places for teaching and research. Medical schools have successfully encouraged VA hospitals to seek the latest equipment and specialized facilities. The 1977 NAS study noted a proliferation of various special care units, for example, nearly 70 cardiac catheterization units (62). Each VA hospital seemed to want its own specialized resources, in part to satisfy its medical school affiliates, even though these resources were frequently underused.

Two other factors have also affected resource allocation, namely, the VA's voluntary relationships with regional and State health planning agencies and the absence of effective utilization review. Under Public Law 93-641, the National Health Planning and Resources Development Act of 1974, the VA was given voting membership on State health coordinating councils and on regional health systems agencies.[4] A VA hospital was supposed to submit an application to the health systems agency for new construction or equipment. The agency made a recommendation to the VA Central Office, which could approve or disapprove without regulatory constraint and did not have to explain its action. NAS recommended that the VA become part of the general health care planning process established for communities and regions (62).

The absence of effective utilization review is a second possible reason for inefficient resource allocation. VA hospitals have not been under the Professional Standards Review Organization (PSRO) program, the peer utilization review for Medicare and Medicaid. The VA moved, somewhat slowly, to establish a VA Health Services Review Organization for quality assessment and utilization review. As part of this initiative, Thompson (90) notes that the VA may have adopted some of the shortcomings of the PSRO program, such as deriving standards for hospitals in peer groups by examining treatment processes, which would identify outlier hospitals but would not pinpoint excesses committed by all facilities in a peer group.

Other social and political forces have constrained the VA's adoption and use of devices. For example, the VA's attempts to increase its CT scanners were criticized in a General Accounting Office report (98) and opposed by Congress in the late 1970s. When, in 1978, the VA moved to purchase 13 new scanners to supplement its existing 24, congressional resistance prompted the VA to withdraw the request. Furthermore, the Office of Management and Budget placed considerable pressure on the VA to reduce hospital beds. The VA reduced them, as a result, from about 121,000 in 1964 to fewer than 90,000 in 1980 (91). (Recent legislation [Public Law 97-174] requires the VA to operate at least 98,000 beds.)

Generally, the social and political pressures on the VA to overadopt devices in some areas of care and to constrain expenditures in others have an additional important implication. The VA's resources may be adequate for its functions, but may not be distributed equitably or efficiently among geographic areas, types of facilities, or functions within and across hospitals. The VA's often sporadic adoption and use of devices and other technologies and patterns of care seem to provide ample evidence of this. The VA has demonstrated international leadership in such areas as cardiac care and radioisotopes. Yet in 1983 fewer than one-third of VA hospitals had CT scanners (40), and the 1977 NAS study found evidence of maldistribution of equipment, basic and specialized services, staff, and beds (62).

NAS also found that some of this poor distribution could be attributed to the VA Central Office and its Service Directors, because some important allocation decisions seemed to rest more on judgment than on explicit criteria. Recent evidence suggests that the VA has not restructured its allocation process to address this problem.

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[4] The main reasons for this legislation were to establish mechanisms for developing national health planning policy and to augment areawide and State planning for health services, manpower, and facilities, in order to curtail the rise in health care expenditures, improve access to care, and ensure quality of care. A non-VA hospital needed to apply for approval of substantial construction and expensive equipment to the local or areawide health systems agency, which made a recommendation to the State planning agency. The State agency approved the recommendation or reversed it with an explanation; the applicant could appeal. Final approval or denial of an application was made by the Secretary of Health and Human Services.

The VA recently decided to purchase a nuclear magnetic resonance (NMR) unit, which is one of the newest advances in medical imaging and diagnosis, and which some experts believe may assume many of the present functions of the CT scanner. As the clinical potential of this new scanning technique becomes better understood, many VA medical centers may want to procure their own units. NMR is an expensive technology, however, costing $1 million or more for the machine alone and necessitating facility modifications that may cost an additional $1 million (84). Because of its cost, policymakers have urged a thorough assessment of its health benefits before widely using it.

The VA Central Office decided to purchase an NMR unit early in 1983. On the recommendation of the Director of Nuclear Medicine, the Chief Medical Director chose to place this unit at the St. Louis VA Medical Center. This particular VA facility was chosen because it represented, in the Service Director's judgment, the best mix of support equipment, staff, and physical location (81).

The decision to place the NMR unit at the St. Louis VA medical center may have been correct, but the NMR decision process has been questioned by observers both within the VA and elsewhere. Explicit criteria for choosing a location were never developed, nor was an expert advisory group formed, nor were protocols developed for an objective evaluation of VA needs.

Early in the adoption process, the VA Medical Research Service proposed a strategy to introduce NMR into the VA system: a solicitation of all interested VA medical centers to submit proposals for an NMR center. These proposals would be evaluated by an ad hoc advisory committee, and their recommendations forwarded to the Chief Medical Director for review and action. Importantly, the review would include studies of the cost effectiveness of NMR compared to more conventional imaging devices (35).

The proposed strategy, however, was not initially considered by the office of the Chief Medical Director. Only in November 1983, after the first NMR unit was being placed in St. Louis, did the office of the Chief Medical Director begin to implement such a strategy. The VA's apparent lack of system in decisions about new technology raises serious concerns about VA resource allocation. Because of NMR's clinical potential and because of its high costs, NMR is an important test of VA policy. At this time, though, it would appear that the VA has not developed a wise policy for acquiring major medical devices, such as NMR.

### Future Acquisition Issues

The VA must continually confront issues about many new devices and other technologies such as NMR, assess their need, demand, and relative value, and make decisions about their purchase and use. This chapter has discussed the VA's current related policies and programs. There is some evidence, however, that VA methods of acquiring devices and other technologies may be in transition.

An internal VA study examined the relationship between technology needs and MEDIPP (15). An earlier section of this chapter examined MEDIPP as a framework for VA planning and discussed its usefulness in identifying VA needs for major medical equipment. In MEDIPP's first year, ending in November 1982, 28 district plans were analyzed, and two significant findings emerged regarding device adoption and use. The first was that, in addition to traditional routing requests, VA districts are unexpectedly using MEDIPP to request the purchase of controlled item equipment. There were specific requests for over 40 major equipment items, including seven CT and six NMR scanners, six cardiac catheterization items, two computerized electrocardiography devices, and digital subtraction angiography equipment. Some districts requested major equipment items through both traditional Central Office channels and MEDIPP. Other districts made no major equipment requests through MEDIPP.

The second finding was that MEDIPP identified about 50 VA-wide issues for future health care delivery. Of those 50, the acquisition of devices (and the larger issue of medical technology) was among the four considered most important.[5] VA administrators and planners believed that both immediate and secondary impacts of technology acquisition are crucial in planning and resource allocation.

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[5] The other issues were (in order) bed levels, geriatric care, and data validity (good recordkeeping).

The findings from the first MEDIPP cycle confirm the potential utility of MEDIPP, not only in planning but also in tracking major equipment adoption and use. As new equipment requests are made through medical district plans, a good evaluation program could guide technologies' diffusion within the VA (15).

One evaluation that might be effective is technology assessment, or comprehensive technology assessment, as it is sometimes called. This form of policy analysis provides information on the effects of a device or other technology, including social, ethical, political, economic, and technical effects. Technology assessment uses various methods and draws on many disciplines. It takes several important factors into account: 1) unintended and unanticipated impacts of technological applications; 2) indirect effects; and 3) the distribution of costs, benefits, and other effects among all interested parties.

Technology assessment has not been used very extensively in the VA health care system. In June 1983, however, the Chief Medical Director of the VA formed a High Technology Assessment Group, which will "determine what course the VA should follow with respect to acquisition of major new technology in the future" (84). As the VA faces changing health care delivery needs and stable or declining health care budgets, some analytical method is needed to address more comprehensively the many factors involved in adopting and using costly equipment. Appropriate evaluation methods are probably needed for several kinds of VA users, from technicians to Service Directors. Such an effort might be very useful to the VA in allocating health care resources more efficiently and equitably.

# Appendixes

# Appendix A.—Acknowledgments and Health Program Advisory Committee

In addition to the advisory panel, this technical memorandum has benefited from the advice and review of experts in rehabilitation, veterans' affairs, and health policy. The staff would like to express its appreciation to the following people for their valuable guidance.

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# Appendix B.—Medical Devices and the Veterans Administration: The Perspective of Veterans' Service Organizations

There have been veterans' service organizations in this country since before the Declaration of Independence. The first, the Society of the Cincinnati, was formed during the Revolutionary War. Today there is no accurate record of all the veterans' organizations in this country (89). They range from small groups in isolated areas to large organizations that play a role in forming national policy. Most of the organizations perform two kinds of services for veterans. They help individual veterans obtain Federal benefits and services and provide their own services to veterans. For their members as a group, they represent veterans' concerns before legislative bodies.[1]

The six veterans' organizations discussed here are active nationally. They all work closely with the Veterans Administration (VA) while providing services, monitoring the VA's activities, and suggesting improvements in VA operations. OTA conducted an informal survey of these organizations' relationships with the VA by talking with their representatives. Views were sought on the VA's responsiveness to veterans' health care needs and the strengths and weaknesses of current VA programs, particularly with regard to prosthetics and rehabilitative devices. Each of the six organizations consulted is briefly described along with their viewpoints, with emphasis on problem areas and suggested improvements. Note that these organizations represent only one perspective on the issues. Their views should be considered keeping in mind that they are consumers of VA health care and therefore not impartial observers.

## Paralyzed Veterans of America

The Paralyzed Veterans of America (PVA) is a national, nonprofit service organization for paralyzed veterans, founded in 1946 and chartered by Congress in 1971.[2] With 11,000 members and 36 chapters throughout the United States, Puerto Rico, and Mexico, PVA is the largest advocate for 25,000 paralyzed American veterans. Although membership is limited to veterans who have spinal cord injury or disease and an honorable discharge (injury may or may not have occurred during military service), PVA also works as an advocate for the other 175,000 nonveteran paralyzed Americans, as well as all U.S. veterans (71). PVA's emphasis is on improved medical treatment and rehabilitation for all those with spinal cord injuries.

PVA was involved in the VA establishment of Spinal Cord Injury Centers in the late 1940s to treat spinal cord injuries and diseases. There are now 19 Spinal Cord Injury Centers across the country, with PVA representatives in each (39).

PVA is also concerned with meeting the posthospitalization needs of both paralyzed veterans and other paralyzed Americans, including accessible housing, specialized transportation, high-quality education, and prosthetic aids for more independent living. PVA's activities are organized around four major programs, for national service, advocacy, legislation, and research.

The national service program operates 46 regional service offices, corresponding to regional facilities of the VA, staffed by national service officers trained to advise veterans and their dependents on their needs, legal benefits, health care (including prosthetics, medication, and rehabilitation), education, housing, and other VA benefits. National service officers also monitor the activities of the VA medical centers in their jurisdictions, including the appearance, condition, and maintenance of the facility; the adequacy and availability of medical equipment; personnel training, retention, and levels; prosthetic availability, fitting, and distribution policies; outpatient treatment and admission procedures; and the hospital administration's long-range plans and goals (68).

PVA's advocacy program is committed to eliminating barriers to disabled people in housing, transportation, employment, education, and rehabilitation. The advocacy department has represented PVA's positions on numerous committees, both public and private, and has participated in several lawsuits, as a friend of the court and as a litigant.

The PVA legislative program considers how changes in laws affect disabled veterans and other handicapped persons and encourages the Government to protect and expand veterans' benefits. PVA monitors and advocates legislation both federally and locally, and testifies at legislative and administrative hearings.

The PVA research program explores ways to improve the care, treatment, and rehabilitation of spinal-cord-injured people and promotes the search for a cure for spinal cord injury. PVA is the largest private supporter of central nervous system research in the United States (68). Through the Technology and Research Foundation, established in 1975, PVA awards research grants and fellowships for research related to spinal cord injury, including basic and applied medical research and research on rehabilitation methods and aids. PVA itself conducts demographic and statistical studies to clarify problems related to spinal cord injuries (71).

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[1] It is estimated that between 3 million and 5 million, out of almost 30 million, veterans in the United States belong to veterans' organizations. It is difficult to establish a more precise figure because many, and in fact, probably most veterans who do belong to an organization belong to more than one (70).

[2] A congressional charter essentially lends prestige to an organization; there are no legal benefits of a congressional charter.

## Disabled American Veterans

After World War I, some disabled veterans formed local self-help groups that eventually became the Disabled American Veterans (DAV), a national nonprofit association established in 1920 and chartered by Congress in 1932. The founders of DAV worked with other organizations toward the legislation for a central Government agency to handle veterans' affairs—the Veterans Bureau, forerunner of today's Veterans Administration. DAV now has 818,000 members and a nationwide network of service programs, in addition to a Vietnam veterans outreach program, a national legislative program, and a national employment program.[3] DAV places special emphasis on meeting the needs of Vietnam veterans. Approximately 25 percent of DAV's members are veterans of the Vietnam War period and Vietnam veterans represent 95 percent of the professional staff, both at DAV's national headquarters and in the field.

DAV's national service program operates much the same as does PVA's corresponding program, with approximately 250 national service officers in 68 offices across the United States, who provide free counseling and claims representation for disabled veterans and their families. In addition, since 1973 DAV has sent Field Service Units to rural and suburban areas to serve veterans and families living too far from DAV offices. All DAV national service officers are disabled veterans with service-connected, wartime disabilities who function as attorneys-in-fact, representing veterans before the Veterans Administration, the Social Security Administration, the Labor Department, and other Federal and State agencies. They provide counseling on disability benefits, rehabilitation programs, and other available services, and help in preparing claims and assembling evidence to support claims.

DAV also provides a Disaster Fund (for disabled veterans needing help because of natural disasters), an Emergency Relief Fund (for disabled veterans facing financial emergencies), and a Scholarship Fund (for children of needy disabled veterans). These programs are available only to veterans with service-connected disabilities, although one need not be a DAV member to apply.

DAV's national legislative program monitors and advocates legislation affecting benefits for disabled veterans and their families, including disability compensation, health care, employment, vocational rehabilitation, and death benefits. DAV also advocates architecture designed for handicapped people. Like PVA's advocacy and legislative programs, this DAV program is active at local, State, and national levels.

Through its national employment program, DAV helps disabled veterans find jobs, supports local employment programs, helps employers and local government officials place disabled veterans in jobs and job programs, and files job discrimination complaints on behalf of disabled veterans. DAV works closely with the National Alliance of Business, the President's Committee on Employment of the Handicapped, and other private and public organizations concerned with creating equal employment opportunities for handicapped people.

## Veterans of Foreign Wars of the United States

The Veterans of Foreign Wars of the United States (VFW) is the Nation's oldest existing veterans' service organization, and one of its largest. It originated from the veterans' groups formed in the early 1900s by veterans of the Spanish American War, the Philippine Insurrection of 1899, and the China Relief Expedition of 1900. Several of these early groups eventually banded together to form a new organization, which in 1914 became the VFW.[4] Since 1914, the VFW has worked for compensation, pension, hospital, and bonus benefits for World War I veterans; the GI Bill of Rights for veterans of World War II, Korea, and Vietnam; and other major laws providing benefits to veterans.

The VFW now has nearly 2 million members; in the past 15 years membership has increased by more than 250,000. Membership in the VFW is open to any U.S. citizen who has served honorably in any overseas engagement for which a campaign medal or ribbon was awarded by the U.S. Government. The VFW has nearly 10,000 posts (local chapters), in the United States, Germany, Thailand, Korea, Japan, France, and other countries (45).

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[3] To qualify for membership in DAV, an honorably discharged veteran must have a disability incurred in wartime military service or under conditions similar to war (23).

[4] The VFW, however, recognizes its founding year as 1899, when the first of the organizations that would become the VFW was formed.

VFW operates a nationwide service network like those of PVA and DAV to aid all veterans and their families (regardless of whether they are VFW members) in filing claims for benefits. It also promotes legislation for veterans' rights and benefits and national security, and sponsors community activities, including programs aimed at stimulating patriotism and an appreciation of national heritage.

## The American Legion

The American Legion is the largest veterans' organization in the United States. It was born at a caucus of the first American Expeditionary Force in 1919 in Paris, with the goal of building an association of veterans "whose primary devotion was to God and Country" (89). The American Legion now has about 2.5 million members, of whom about 25 percent are Vietnam veterans.[5] Its Auxiliary boasts an additional 1 million members (89). The American Legion has seven programs that have remained essentially unchanged since the organization's beginnings. The programs are for veterans' affairs and rehabilitation, children and youth, Americanism, national security, foreign relations, legislation, and economics.

The American Legion's main concern has always been the "welfare of veterans and their families." Its programs for veterans' affairs and rehabilitation, children and youth, and economics are all intended to serve veterans and their families in various ways.[6] Its other programs--except for those of the Legislative Division,[7] which promotes issues of interest to the organization (including veterans' rights and benefits)—do not directly benefit veterans. Rather, they further the organization's ideals of patriotism and good citizenship, and advocate its views on national security and foreign policy.

Through its veterans' affairs and rehabilitation program, The American Legion operates a nationwide network of 16,000 service officers who provide help in preparing and filing claims for VA benefits (like the service networks of other veterans' organizations). This program also offers advice and representation in cases before the VA's Board of Veterans Appeals and the Department of Defense Boards for discharge review, and in correcting military records. These services are provided free, regardless of whether the veteran is a member of The American Legion. In addition, the program employs six field representatives who regularly conduct onsite visits in the VA's 172-hospital system, much like PVA's hospital monitoring (82).

## American Veterans of World War II, Korea, and Vietnam

The American Veterans of World War II, Korea, and Vietnam (AMVETS) was founded in 1944 and chartered by Congress in 1947. Although AMVETS was originally formed for veterans of World War II, in 1966 its charter was amended to include veterans of the Korean War and Vietnam. AMVETS now has about 200,000 members, of whom about a third are Vietnam veterans.[8]

AMVETS' goals and services are very similar to those of The American Legion and the VFW. As a service organization, AMVETS' primary commitment is to serving veterans and their families. Its service officers are stationed at VA regional offices and medical facilities in every State. These service officers are trained professionals who offer counseling and representation to all veterans and help them obtain the benefits to which they are entitled, including compensation, education, employment, hospitalization, and rehabilitation (162). AMVETS also participates in the VA's Voluntary Service Program (as do some other veterans' organizations), whose volunteer workers provide services for hospitalized veterans.

AMVETS also provides many community services such as drug abuse education programs, voter registration drives, programs to promote safe driving habits, and a college scholarship program for needy children. Some of AMVETS' community service projects are also intended to encourage patriotism, such as the National Americanism Essay Project it sponsors, and the AMVETS Memorial Carillons in national cemeteries and at historic sites throughout the United States.

## Blinded Veterans Association

The Blinded Veterans Association (BVA) is a nonprofit organization founded in 1945 by a group of veterans blinded in World War II. BVA was incorporated in 1947 and in 1958 was granted a congressional charter. Almost 5,000 of the nearly 50,000 blind veterans in this country belong to BVA.[9] Some of these blind veterans also have other disabilities such as a hearing loss or missing limbs.

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[5] Any honorably discharged veteran who served in World War I (Apr. 6, 1917, to Nov. 11, 1918), World War II (Dec. 7, 1941, to Dec. 31, 1946), the Korean War (June 25, 1950, to Jan. 31, 1955) or the Vietnam War (Dec. 22, 1961, to May 7, 1975) is eligible for membership in The American Legion.

[6] Although the objectives of the program for children and youth have grown to include improved social and economic conditions for all children the original purpose of this program was to ensure the well-being of the children of deceased and disabled veterans.

[7] The Legislative Division is the lobbying arm of The American Legion. Although other issues also get vigorous support from this division, legislation for veterans' benefits specifically and the economic well-being of veterans generally is given priority attention.

[8] Membership in AMVETS is open to any honorably discharged American veteran who actively served in the Armed Forces between Sept. 16, 1940, and May 7, 1975. Those who entered the service for the first time on or after May 8, 1975, are not now eligible for AMVET membership, but legislation is pending to open AMVETS membership to all honorably discharged veterans who served in the Armed Forces from May 7, 1975, to an indefinite future date.

BVA operates much like the other veterans' organizations by providing help to individuals through a nationwide service network and by representing the interests of blind veterans in promoting legislation. BVA has two major service programs, the Field Service Program and the Outreach Employment Program. Both are provided under contracts with the Federal Government: the Field Service Program under contract with the VA and the Outreach Employment Program under contract with the Department of Labor. There are 37 BVA regional groups that provide help at State and local levels.

BVA's Field Service Program is unique in that blind veterans are actually sought out by the field representatives and offered help. BVA obtains the names of blind veterans from the VA and hospital records and through word of mouth. A field representative then visits the veteran and encourages him or her to seek whatever assistance is appropriate. The program employs 10 field representatives, all blind veterans themselves, who help blind veterans in obtaining benefits, including disability compensation or pension, rehabilitation and vocational training, and prosthetic equipment and training in its use. The representatives also counsel the veteran's family and help them to take advantage of existing community programs. This program serves as an adjunct to the VA's 76 Visual Impairment Service Teams at VA medical centers, who are responsible for reaching as many blind veterans as possible to provide them physical examinations and rehabilitation (91).

The Outreach Employment Program makes use of regional employment representatives who help blind veterans by finding prospective employers, providing advice on resumes and job applications, keeping the veterans informed of potential job opportunities, and offering counseling in cases of job discrimination. The program also tries to convince employers, through public service advertising and directly, to hire blind veterans.

## Observations on the Veterans Administration Health Care Delivery System

The veterans' service organizations interviewed for this appendix believe that the Veterans Administration is doing a more than adequate job of tending to the health care needs of veterans in the United States. Some problems were noted, although in many cases efforts are already being made to alleviate them. Comments on specific VA departments follow.

### Rehabilitation Research and Development Service

The VA's Rehabilitation Research and Development Service (Rehabilitation R&D) is primarily responsible for the research, development, and evaluation of new devices, techniques, and concepts in rehabilitation.[10] Such activities generally focus on the three most prevalent service-connected disabilities of veterans: prosthetic aids for amputees, especially lower-limb prosthetics (which represents about 40 percent of the Service's budget); aids for veterans with spinal cord injuries, with special emphasis on wheelchairs (representing about 30 percent of the budget); and sensory aids, including aids for the visually impaired (representing about 30 percent of the budget)(8). Although the dollar amount allocated to Rehabilitation R&D rose 40 percent from fiscal year 1982 to fiscal year 1983 (a $2.9-million increase), this Service receives only 6.4 percent of the VA research and development budget (see table 2 in ch.3).

PVA, DAV, and BVA all feel that greater funding should be provided for research sponsored by Rehabilitation R&D. However, they disagree on which areas should be emphasized. PVA would like to see more R&D conducted on aids for spinal-cord-injured veterans, DAV on prosthetics, and BVA on sensory aids for the blind (33,39,161).

All the organizations noted that positive changes have been made in the last few years, such as increased funding for Rehabilitation R&D and greater participation of veterans' organizations in setting research priorities. The VA recently held three informal sessions to discuss research priorities in upper- and lower-limb prosthetics, speech pathology, audiology and aids for hearing-impaired veterans, and functional electrical stimulation. Nearly 50 people from across the country participated in each session, including experts in the relevant fields, VA representatives, physicians, device manufacturers, and representatives of all the major veterans' organizations.

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[9] Membership in BVA is open to all veterans with service-connected blindness. Blinded veterans with non-service-connected blindness are eligible for associate membership.

[10] Rehabilitation R&D and other VA programs for research and development are discussed in ch. 3 of this technical memorandum. The testing and evaluation of devices is carried out by the VA Prosthetics Center in New York City and the VA Marketing Center in Hines, Illinois (see also ch. 4).

PVA, DAV, BVA, AMVETS, and The American Legion are also represented on the VA Rehabilitation R&D merit review panel, which recommends research priorities and reviews research proposals and results.

### Prosthetics and Sensory Aids Service

The Prosthetics and Sensory Aids Service (PSAS) is generally responsible for providing eligible veterans with the prosthetic and rehabilitative devices and sensory aids that they need for independent living. PSAS is also involved with the research, development, testing, and evaluation of commercial devices, as well as procurement and supply. Veterans' organizations commended the VA for increasing the size of PSAS staff, for recognizing the need for training VA field representatives and developing a comprehensive training program, and for encouraging more involvement with veterans' organizations. Some of these initiatives have already produced results, others will require more time.

Several veterans' organizations noted that some of the information available on benefits is not accurate. Inadequate training of field representatives is not the main reason for this, however, but rather that the PSAS Program Operating Manual requires much revision. The manual, which describes the process of issuing devices, including eligibility requirements and verification of eligibility, has not been revised since 1956. The field representatives' reliance on an incomplete and outdated manual resulted in the inconsistent application of national policy and arbitrariness in the representatives' interpretation of rules. The manual is now being revised, with help from all major veterans' organizations.

The most frequent complaint about PSAS concerns the long delays in providing prosthetic and rehabilitative devices to veterans. All the organizations interviewed gave examples of unacceptable delays between the order and actual delivery of devices. For example, a cane was delivered only after several months and a custom-designed wheelchair only after a year. Long delays for repairs were also noted, such as hearing aid and eyeglass repairs that took up to 5 weeks. These delays are primarily attributed to the fact that all orders must go through the Office of Procurement and Supply's Prosthetics Distribution Center in Denver, Colorado.

It is possible that a decentralized distribution system would be more effective. The VA considers it more cost effective to stock large quantities of devices at one center. However, a complete analysis should take into account inventory costs, the costs of paperwork involved in placing orders, and the time that disabled veterans spend without devices essential to their everyday activities. The veterans' organizations suggested that PSAS have greater flexibility to contract with local suppliers in distributing devices. The VA Office of Inspector General audited the Prosthetics Distribution Center in 1983 (138) and made recommendations to improve the efficiency and economy of the distribution and repair functions of the Prosthetics Distribution Center. However, the recommended changes must be negotiated with the Department of Medicine and Surgery before taking action.

### The VA Prosthetics Center

The VA Prosthetics Center (VAPC) has been widely viewed by veterans' groups as having serious organizational problems, largely because of its autonomy.[11] VAPC now has direct line authority through PSAS, which could help solve some of these problems. VAPC's original goals were to conduct research and development in rehabilitation engineering, to evaluate and test commercially available assistive devices, to provide direct patient care for difficult prosthetic and orthopedic cases (i.e., customized devices), and to manufacture and distribute orthopedic footwear and prosthetic and orthotic devices. These are still VAPC's responsibilities, with the exception of R&D, but there have been problems with VAPC's providing direct patient care.

VAPC Special Clinic Teams were intended to provide expert fitting and construction of prostheses for the most difficult prosthetic cases.[12] People from across the Nation were to be sent to VAPC when they needed special treatment. According to DAV, however, this program has not been successfully implemented. In addition, plans to introduce five additional Special Clinic Teams in other hospitals across the country have been late in implementation. These additional teams were to be trained and in place by October 1984. Instead, as of November 1984, seven teams have been identified, but the teams are not complete and more training is needed. The new target date is March 1985 (13).

The Chief Medical Director proposed that VAPC's special patient care services be moved in January 1983 from present facilities in New York City to the Manhattan VA Medical Center, on the expectation that a hospital setting would be more conducive to direct patient care. DAV has questioned the proposed location on the grounds that it may not be accessible to handicapped veterans. The proposal to move VAPC is still being discussed and Congress must be notified prior to any action (13,164).

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[11] VAPC is discussed in chs. 3 and 4.

[12] Special Clinic Teams are discussed in ch. 3.

Along with other VA departments, VAPC has also been involved with setting standards and evaluating commercially available devices. Prosthetic aids, wheelchairs, and aids for blind and hearing-impaired veterans are all produced mostly by private manufacturers and provided to the VA through contracts. Many commercially manufactured devices are evaluated to ensure that they meet VA standards prior to the VA's adopting them for use. PVA and DAV indicated, however, that some new products are constrained by the VA's more specific standards.

As far as the VA's evaluation is concerned, PVA, DAV, and BVA all mentioned that inefficiencies in the system result in delays, and that the device needs of veterans are not always met because of inconsistent and restrictive policies and standards. PSAS initiated the Prosthetic Technology Evaluation Committee in early 1982 to address problems in VA evaluations.[13] PVA and DAV have permanent representatives on this committee, which is responsible "for assessing and ranking the legitimacy and appropriateness of evaluation proposals and for assessing and approving the results of clinical evaluations." Other veterans' organizations are kept informed of the committee's activities and invited to participate in its meetings. All the organizations feel that the committee is a first step in the right direction, that improvements are already evident, and that further progress will take time, but can be expected.

## Summary and Conclusions

Although the veterans' organizations discussed here have different eligibility requirements, different degrees of involvement in political issues, and different programs for veterans, all of the organizations emphasize the needs of their particular members, and these needs are often those of all veterans.

The delivery of high-quality rehabilitation services and medical care, including prosthetic and rehabilitative devices, is a main concern of these organizations. All have representatives in place at some, if not all, VA medical facilities. These representatives function like consumer representatives for the VA, determining the needs of veterans, assessing their eligibility for VA benefits, and helping them obtain the benefits. In addition, representatives of some organizations monitor the activities of VA health care facilities to promote high-quality care.

Since veterans' service organizations are so closely involved in the VA's delivery of health care, both as participants and observers, their perceptions of VA programs are valuable. These organizations generally feel that they have an excellent working relationship with the VA. Although there are still problems, the view of these organizations seems to be that the VA is increasing efforts to involve veterans' groups in planning and policy decisions and to respond to the groups' concerns. All these organizations meet regularly with the VA, and some have representatives on various VA panels. In addition, informal meetings are held between veterans' organizations and the VA as issues arise.

Not surprisingly, these organizations would like to see greater Federal allotments to the VA, as well as greater VA allotments to the programs serving their members. Another consensus view is that there are long delays in providing and repairing prosthetic and rehabilitative devices. Although a certain amount of procedure and delay has been expected because of the size of the VA bureaucracy, improvements could be made. Through cooperation and discussion between the VA and veterans' service organizations, progress is being made to improve these services as funds permit.

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[13] The Prosthetics Technology Evaluation Committee is discussed in ch. 4.

# Appendix C.—Veterans Administration Procurement and the Market for Medical Equipment[1]

This appendix describes and analyzes the ways that Veterans Administration (VA) procurement of medical equipment affects and is affected by conditions of demand and supply in the markets for X-ray equipment, computed tomography (CT) scanning equipment, digital imaging equipment, nuclear diagnostic equipment, nuclear magnetic resonance (NMR) and positron emission tomography (PET) scanning devices, ultrasound diagnostic equipment, patient monitoring and electroencephalography (EEG) and electrocardiography (ECG) equipment, and hemodialysis equipment. The discussion encompasses the ways procurement policies of the VA affect the prices and products that are offered and the practices of private buyers. Manufacturers' comments on VA procurement are also summarized.

This study is based on data available through the VA Marketing Center (VAMKC) about its procurement. Although important national market structure data exist, most are available only in the form of 4-digit SIC codes, which are too broad a classification for the analysis here.[2] In fact, all types of equipment examined in this study fall within a single 4-digit SIC code, SIC 3693, electromedical and electrotherapeutic equipment.

Some Bureau of Census data are available in the finer 5-digit and 7-digit codes, but they suffer from several problems: First, data are withheld at these levels because of Bureau requirements to maintain confidentiality of individual firms' data; second, some important structural data are not reported at all at these levels of analysis; and third, there begin to be severe problems in the data reliability of plants that produce many products.

Private proprietary sources of data are not bound by the same confidentiality requirements as the Bureau of the Census, but they tend to be incomplete and are frequently inconsistent (3).

Because of VAMKC contractual reporting requirements, however, the characteristics of specific equipment markets can be reconstructed, including information on product market concentration, market shares of individual firms, and market share instability. (When findings are reported here, care has been taken to ensure their confidentiality.) In addition, data gleaned from interviews with manufacturers' representatives have been analyzed along with VAMKC data for a fuller interpretation.

## Diagnostic X-Ray Equipment

X-rays are a highly penetrating form of electromagnetic radiation of much higher frequency than visible light. They are generated in evacuated glass bulbs called X-ray tubes that contain two electrodes, an anode and a cathode. High voltage applied between the two electrodes causes electrons to flow from the cathode to the anode, and X-rays are produced as the electrons strike the anode. Since substances vary in their opacity to X-rays, X-rays that have passed through a body can provide information on its internal structure (63). In standard radiography, X-rays that have passed through the body strike a sensitive photographic film, and the resulting picture reflects the structures through which the X-rays have passed. A conventional radiograph is effectively a shadowgraph, a projection of the X-ray absorption of a three-dimensional body onto a two-dimensional detector. (Standard X-rays are also called "projection X-rays.") In fluoroscopy, the detector is a fluorescent screen rather than photographic film. In modern fluoroscopy, X-rays are detected by a phosphor surface next to the surface of a photoemitter, to intensify the image. The final image can be viewed directly or camera recorded.

Conventional radiography provides excellent spatial resolution but rather poor contrast resolution. In other words, objects of different opacity to X-rays than surrounding material are quite distinct in X-ray images, but it is difficult to discern even a large target object if its opacity to X-rays does not differ significantly from that of surrounding material. As a result, except in regions of low absorption, namely the chest, breast, and extremities, conventional radiography is unsuited for characterizing soft-tissue detail (75).

### General Demand Characteristics

**Supplies v. Equipment Costs.**—Annual expenditures on X-ray film and other supplies depend on how much X-ray equipment is used. In a large hospital, the annual cost of supplies can easily be as great as the purchase price of the equipment (21,25). X-ray film, film development chemicals, and other supplies are typically purchased independently of X-ray equipment.

**Equipment Purchase Price.**—X-ray equipment varies greatly in price depending on its characteristics. A simple unit may cost as little as $30,000, while the equipment for a fully appointed procedures room may cost well over $1 million. Peripheral equipment is also required, such as developing rooms, viewing equipment, and cabinets for storing X-ray photographs.

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[1] Based on a paper prepared for OTA by Ralph Bradburd (14).

[2] SIC codes are Standard Industrial Classification codes, which are used by the Bureau of the Census of the Department of Commerce to classify products for the Census of Manufactures, which provides the most comprehensive statistics on medical device industries (see 105).

**Servicing and Technical Support.**—The need for technical support and servicing of X-ray equipment increases with its complexity. Sophisticated X-ray equipment may require up to 8 weeks for installation and calibration (21). For annual service contracts, manufacturers quoted costs ranging from 5 to 14 percent of equipment purchase costs. Servicing costs and "downtime" of equipment are both important considerations in purchasing, and service availability can support a VA hospital's "brand name justification" for purchasing equipment (which is explained below).

### The VA Market: Demand and Supply

**VA Demand.**—VA X-ray equipment purchases are channeled through the VAMKC's Radiological and Nuclear Equipment and Supplies Division. The VAMKC negotiates annual contracts with vendors, and when VA medical centers (or other units that purchase through the VAMKC) are authorized to purchase X-ray equipment, the VAMKC places the order, arranges for direct delivery to the medical center, and administers the contract (40).

X-ray equipment accounts for more direct delivery medical equipment capital expenditures than any other single equipment category, and represents a substantial annual budget item. As a proportion of medical equipment expenditures, those for X-ray equipment have been falling, representing 71 percent of total medical equipment expenditures other than through the Federal Supply Schedule (FSS) in 1979, 69.6 percent in 1980, 50.2 percent in 1981, and 46.9 percent in 1982.[3] Yet the corresponding absolute dollar amount in 1982, over $59 million, was larger than that in any of the previous 3 years (131,132).

The VAMKC manages direct delivery purchases of X-ray equipment for a number of Government agencies other than the VA, including the Public Health Service. Even so, the VA accounted for 91.3 percent of VAMKC's total direct delivery X-ray equipment expenditures in 1979, 78.2 percent in 1980, and 73.8 percent in 1981 (131).

**VA Demand Relative to the National Market.**—The VAMKC appears to be a significant part of the national market for X-ray equipment. The VAMKC requires that vendors disclose total annual sales of the equipment covered in their annual contracts. Although incomplete, the data made available to OTA by the VAMKC indicate that it purchases roughly 5 to 10 percent of the X-ray equipment of companies on annual contract. Companies apparently vary in the proportion of the X-ray equipment sales they make through the VAMKC, for one company below 5 percent, for another over 10 percent (132). For many, but not all companies, the VA is either their largest or one of their largest customers (4,21,25,48,86).

**VAMKC Demand Variability.**—Total expenditures for X-ray equipment orders processed by the VAMKC are highly variable. From 1979 to 1980, they fell by 35.6 percent, and from 1980 to 1981, they fell an additional 37.2 percent. Finally, from 1981 to 1982, they rose by 297.6 percent. The variability of VA demand for X-ray equipment was somewhat greater than that of other agencies that purchase through the VAMKC. VA purchases fell by 44.9 percent from 1979 to 1980, and by 40.8 percent from 1980 to 1981 (131). (Available data do not permit the calculation of the corresponding 1981-82 percentage change.) Such demand variability is high compared with most American industries (93). Its effect on the market will be discussed below.

**Suppliers to the VA Market.**—Many major manufacturers of X-ray equipment have had VAMKC annual contracts in the past 3 years, including (in alphabetical order) CGR Corp., General Electric Co., General X-ray, H. G. Fischer, Orthopedic Equipment, Philips Medical Systems, Picker International, Raytheon, Siemens Corp., and Xonics Medical Systems. However, this VAMKC market is relatively concentrated: Four firms accounted for almost 95 percent of sales to the VA in 1982 (132). In addition, if vendors are ranked by sales volume for 1979 through 1982, the same four firms are always found at the top, with none moving by more than one rank (131,132).

Taken alone, these data might indicate lack of competition in the market. However, further data analysis shows that, although rankings by market share have not changed much, the market shares themselves have. In measuring market share changes, the greatest possible sum of the absolute values is 200. This is the value resulting should the market change hands completely, with every firm with any sales in the first period having none in the second and other firms entirely capturing the market. Table C-1 shows the significant annual changes in market shares during the sample period.

There are several possible explanations of the observed volatility in market shares. One is that the

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[3] The FSS program is administered by the Office of Federal Supply and Services of the General Services Administration. VAMKC is the commodity manager for this program's Group 65, Medical, Dental, and Veterinary Equipment and Supplies. VAMKC establishes contracts with manufacturers of this equipment under the policy guidance and procurement regulations of the General Services Administration. (This arrangement is discussed further in ch. 5.)

**Table C-1.—Sum of Absolute Values of Annual Percentage Changes in Vendors' VA Marketing Center X-ray Equipment Market Shares, 1979-82**

| | 1979-80 | 1980-81 | 1981-82 |
|---|---|---|---|
| Sum of absolute values...... | 26.4 | 45.8 | 29.3 |
| As a percentage of maximum possible value (200) ....... | 13.2 | 22.9 | 14.6 |

SOURCES: U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished data, Hines, IL, 1983; and U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished information from vendors' 1982 contracts, Hines, IL, 1983.

individual buyers of X-ray equipment prefer particular companies' products, and it happens that the purchase cycles of these buyers alternate to produce the observed shifts. Although the data do not permit a test of this hypothesis, it seems unlikely. An alternative, and more likely, explanation is that the firms aggressively compete with each other in price or product performance, with the lead in either or both of these dimensions, and hence the market share, changing hands from year to year.

## CT Scanning Devices

CT scanners are a form of X-ray equipment. As in standard radiography, X-rays are generated and detected, and the attenuation of the X-rays as they pass through the body provides information about the structures through which they have passed.

In CT scanning, the X-ray beam is passed through a collimator (a device for producing a beam of parallel rays of light or other radiation) that forms the beam into a thin fan in a plane perpendicular to the long axis of the body. On the other side of the body is an array of X-ray detectors. Each of these detectors produces a charge signal proportional to the X-ray energy it absorbs. Signal strength is a function of the attenuation of the X-ray along the path between the detector element and the X-ray source.

To produce a cross-sectional image, depth information is obtained by rotating the source and detector array around the body axis while taking projections of the same section from several hundred different angles. The data from each projection are "digitized" and processed. A series or "stack" of contiguous CT images contains all the data necessary for constructing a variety of quasi-three-dimensional forms (75).

CT scanning devices help overcome two limitations of standard X-ray equipment. First, they allow the diagnostician to obtain a view of a cross-section of the body, as opposed to a projection that provides only information on the total accumulated attenuation of the X-ray beam as it passes from one side of the body to the other. A tumor or lesion directly behind a bone as the body is viewed may not be detectable in a standard X-ray. Also, standard X-ray equipment usually cannot determine the depth of a tumor or lesion, but a cross-sectional view can. In addition, because the detector absorption data are digitized and can be processed, greater contrast resolution is possible (as explained in the discussion of image data processors below). CT scanners are extremely important in detecting tumors, in determining the optimal path for radiation therapy, and in other uses.

### General Demand Characteristics

**Supplies v. Equipment Costs.**—Accurate data are not available on the annual costs of supplies for CT scanners. However, because these scanners are much more expensive than standard X-ray equipment, and because they use digital image recording rather than expensive X-ray film, the cost of their supplies should be smaller relative to equipment costs compared with standard X-ray equipment.

**Equipment Purchase Price.**—The list price of a CT scanning device generally varies between $600,000 and $1,500,000 depending on its manufacturer and characteristics. These prices have begun to fall as the market has matured and the cost of data-processing components has fallen (40).

**Servicing and Technical Support.**—CT scanners are extremely sophisticated equipment and, to perform properly, must be very finely adjusted. (The VA hires an outside consultant, a physicist, to inspect installed CT scanners.) As a result, both technical support and servicing are extremely important. One vendor quoted a price of $85,000 for the annual service contract on a CT scanner with a list price of about $1 million, or about 8.5 percent of the equipment's purchase price (4,25,42,86).

### The VA Market: Demand and Supply

**VA Demand.**—CT scanning devices are purchased through the VAMKC, rather than through the usual FSS, decentralized contracts, or direct delivery programs (all described in ch. 5). Purchases of CT scanners must be approved by the VA Central Office in Washington, DC. The Central Office has ranked VA hospitals by their need for CT scanners. Funds for the scanners are budgeted in the VA Central Office and are provided centrally, not as usual through hospital funds. Purchases are delayed until a sufficient number are possible, so a group purchase can be made with significant savings. The VAMKC then requests bids for equipment meeting its specifications.

In 1982 the VAMKC requested a bid for purchase of 23 CT scanners, 21 for VA hospitals and 2 for the Air Force. The list price for the equipment of the winning bidder was $1,359,000 per unit; the VAMKC procured the equipment at $917,730 per unit. An additional $4.4 million worth of CT scanners were bought in the same year from another company. In 1983, the VAMKC purchased 24 CT scanners through similar bidding. In that year, the list price for the equipment purchased was $1,383,500 per unit; the VAMKC procured the equipment at $829,950 per unit (40).

CT scanners have accounted for a growing proportion of VAMKC-procured equipment costs. In 1979 CT scanners represented 6.1 percent of non-FSS equipment expenditures; in 1980, 13.1 percent; and in 1981, 28.2 percent. In 1982 CT scanners accounted for 20.2 percent of total non-FSS equipment procurement, a somewhat smaller percentage than the year before, but a higher total dollar commitment, $25,512,122 compared to $8,386,270. Since 1980 CT scanners have accounted for more VAMKC procurement dollars than any other category of equipment except X-ray equipment, with most of this CT equipment going to VA hospitals (table C-2). In 1983 VAMKC procurement of CT scanners totaled $19,918,800 (40,132).

**VA Demand Relative to the National Market.**—As mentioned above, CT scanners have not been purchased through the usual VAMKC annual contracts. As a result, there is much less information to estimate the relative importance of VA procurement in the national market. According to a representative of Siemens, the CT market is now about 600 units per year (for all manufacturers), down from 750 per year a few years ago (86). If this number is accurate, VAMKC procurement probably does not account for more than 4 to 5 percent of total national expenditures on CT equipment.

In this market, the VAMKC may also not be some manufacturers' largest account. Nonetheless, the total dollar volume of VAMKC CT procurement—almost $20 million—may be high enough for VAMKC's procurement practices to influence manufacturers' behavior, if not as much as in other markets.

**Table C-2.—Annual VA Marketing Center Procurement of CT Scanning Equipment, 1979-82**

| | 1979 | 1980 | 1981 | 1982 |
|---|---|---|---|---|
| Total annual CT procurement by VAMKC ($ millions) . . . | $3.2 | $4.5 | $8.4 | $25.5 |
| VA proportion of total VAMKC procurement . . | 100% | 20.7% | 88.4% | N.A. |

SOURCES: U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished data, Hines, IL, 1983; and U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished information from vendors' 1982 contracts, Hines, IL, 1983.

**VAMKC Demand Variability.**—VAMKC procurement of CT scanning devices has fluctuated from year to year, but much of this fluctuation seems more appropriately characterized as growth rather than demand instability, certainly in the period from 1979 to 1982. In any case, given that VAMKC procurement is a small fraction of the national market, a drop in VAMKC orders, such as available data indicated for fiscal year 1983 (from 25 to 24 scanners), is unlikely to have an impact on manufacturers.

**Suppliers to the VA Market.**—A number of major companies produce CT scanning equipment, including CGR, General Electric Co., Picker International, and Siemens. Since 1979 the VAMKC has purchased CT equipment from General Electric, Pfizer, and Picker International (Pfizer has since left the CT market) and some equipment from Technicare, a subsidiary of Johnson & Johnson, for use with CT equipment. In 1982 a number of companies responded to the VAMKC request for technical proposals to supply CT equipment. Only two of those companies' proposals met the necessary technical specifications. Those two companies were then issued an invitation for bid. Of the two companies that received an invitation for bid, only one company's product passed the testing for specifications, and that company received the contract. (There was a second round of bidding in 1982, with different specification requirements, to replace five CT units purchased in 1979.) In 1983 three companies submitted technical proposals that met specification requirements; those three companies received an invitation for bid. One of the three companies' products did not pass testing, and the contract was given to the lower of the two remaining bids. Thus, in both 1982 and 1983, one firm received either all or most of the orders (40).

It is difficult to say whether the number of potential CT equipment suppliers to the VA market will increase or decrease in the next few years. As the market matures, it is likely that some firms now active will exit the market. On the other hand, it is likely that the equipment of more of the firms remaining will meet VAMKC specifications. Thus, it is hard to predict whether competition in the VA market will increase or decrease.

## Digital Image Processing Equipment

Digital image processing is a technology that reconstructs and enhances images based on data stored electronically in digital form. The system is perhaps best explained by comparing it with the technologies it is replacing. In traditional projection radiography, for example, the X-rays passing through the subject strike an X-ray sensitive photographic film. The chemicals on the film are exposed (i.e., darkened) at particular locations depending on the attenuation of X-ray beams as they pass through the subject on their way from their source to the film. In a digitized projection X-ray system, the photographic film is replaced by a grid of electronic detectors that transmit their data on X-ray exposure to a computer, where the data are recorded in digital form. These recorded data can then be processed in a variety of ways and used in reconstructing images. (The familiar computer-printed pictures of the Mona Lisa and Snoopy are examples of image production from digital data, though these computer programs are vastly less sophisticated than those used in medical imaging.)

In digital fluoroscopy, a photoemitter is connected to an image-intensifying system, which creates a video signal that is digitized, stored, and processed. A television monitor driven by a digital display controller then converts the processed information into displayed brightness (75).

Digital image processing offers a number of important advantages over standard radiographic and fluoroscopic techniques and is being applied to ultrasound techniques as well. Notably, this processing can vary the brightness and contrast of a picture so a diagnostician can focus on particular features. As mentioned in the discussion of X-ray equipment, contrast resolution is a problem in standard radiographic techniques. Because the film must record a wide range of X-ray attenuation occurring between the source and the detector, it is often difficult if not impossible to distinguish two objects similarly opaque to X-rays in an X-ray photograph. The advantage of digital image processing is that signals representing a narrow range of X-ray attenuation can be processed to obtain high contrast. This enhancement is like that of a medical thermometer compared to an outdoor thermometer. The outdoor thermometer must record temperatures anywhere from −30° to over 100° F, a very wide range; a medical thermometer can be more sensitive since it only covers a range from 94° to 108° F. Similarly, one may adapt a digital image to focus on a narrow range more sensitively.

There are other advantages of digital image processing as well. It can also be used for edge enhancement and to increase the clarity of the X-ray image. Its greater sensitivity makes possible less X-ray exposure, and the time diagnosis takes is also reduced by eliminating the time-consuming step of film development.

One of the most important medical applications of digital image processing is in angiography (103). In angiography, a catheter is threaded through a vein or artery until properly positioned and a dye that is opaque to X-rays is injected. Subsequent X-rays of the injected region highlight the blood vessel passages, revealing arterial blockages, constrictions, and other signs of atherosclerotic disease. Angiography requires minor surgery, however, and is not without risk; an average of 2 in 1,000 patients die from complications (77).

Digital image processing substantially reduces the risks of angiocardiography and arteriography. In either procedure, dyes injected into the bloodstream begin to diffuse through the bloodstream, and using standard X-ray techniques this meant that dye had to be injected very close to the location of interest, requiring invasive surgery. Digital image processing, however, can enhance the information about the flow of dye. The new techniques can sense far lower amounts of dye than standard equipment, which allows the dye to be injected in peripheral veins. Very revealing images of interior structures can be created using digital subtraction. First, an X-ray image of an area is taken before injecting the dye and the pattern obtained is stored on computer disks or tapes. Then the dye, usually iodine, is injected, and as the dye passes through the area's arteries, a television monitor displays a pattern representing the difference, point for point, between the images before and after injection. In this way, a much less cluttered picture is created (58).

Another important advantage of digital image processing is that its operating costs are much lower than those of standard radiography. It does not require expensive X-ray film, the annual costs of which can be as great as the capital cost of standard radiographic equipment. Also, because images are stored on such media as magnetic tape or disks in very little space, the large storage facilities now required are no longer needed (25,37). In addition, the diagnostician can retrieve stored X-rays almost instantly from a computer terminal.

Because of the enormous and rapidly growing advantages of digital imaging, the markets for radiographic and fluoroscopic equipment are now unstable. One manufacturer's representative predicted that the entire imaging market could be captured by digital imaging within 5 years (25).

### The VA Market: Demand and Supply

**VA Demand.**—In discussing VA demand for digital image processing equipment, it is necessary to distinguish between such equipment that is an integral part of an X-ray system and that called "digital add-on" equipment, which is appended to an existing system to "digitize" it. It is difficult to determine the extent of total VAMKC procurement of digital image processing equipment from available VAMKC documents. The available documents indicate that in 1982 the VA purchased $342,261 worth of digital radiography equipment and $438,900 worth of digital fluoroscopy equipment, for a total of $781,161, or just slightly more than 0.6 percent of the total VAMKC non-FSS expenditures for medical equipment. However, an unknown part of the expenditures for "X-ray equipment" may actually represent such imaging equipment purchased as part of a system (132). In this discussion we will focus on VAMKC procurement of digital "add-on" equipment.

**The Problem of Mixed Systems.**—Perhaps the most important feature of the market for digital add-on equipment is the problem of putting together the products of different companies into a coherent system. VAMKC procurement personnel and manufacturers' representatives indicate their concern about assigning responsibility for equipment breakdowns, particularly during the warranty period. They fear that when a system does not function properly, each of the companies will place the blame on a component produced by the others. In addition, there is the problem of coordinating the delivery of mixed systems, and especially, of determining which manufacturer is responsible for connecting the components. Finally, there are the issues of service costs and the larger discounts typically offered when the VAMKC purchases an entire system from one manufacturer (40).

As a result of these complications, the VAMKC strongly prefers to purchase complete X-ray systems rather than purchase their components from different manufacturers. When the VAMKC does purchase digital add-on equipment, it prefers to purchase this equipment from the same manufacturer that produced the system (40). This preference probably reduces the number of vendors to the VA market, which may increase the costs of the digital add-on equipment. Available documentation does not indicate if the impact of this preference is significant, and if it is, whether or not the above-mentioned difficulties with mixed systems still make the preference for avoiding mixed systems the most cost-effective strategy.

**Suppliers to the VA Market.**—There are probably 30 or 40 manufacturers of digital image processing equipment today (37). However, many of them produce only add-on equipment, and thus, for the reasons discussed above, may have some difficulty selling their products through VAMKC. In 1982 the VAMKC purchased digital image processing equipment from only two companies (132).

## Nuclear Diagnostic Equipment

In diagnostic nuclear medicine, pharmaceuticals tagged with a gamma-ray-emitting isotope are administered to a patient. The steady-state or dynamic distribution of the isotope in the body is then determined by an imaging system. The most common imaging system is the "gamma camera," which produces a projection image. It is also possible to combine cross-sectional techniques and isotope imaging in emission computed tomography, in which one or many gamma cameras rotate around the patient and collect and store data for many projection images. Techniques like those used in CT are then used to create cross-sectional images.

Diagnostic nuclear medicine has a number of medical uses. It requires only a low radiation dose and is particularly suited to the study of cardiac dynamics and to whole-body imaging, which can determine the extent of certain diseases (75). Nuclear medical equipment is commonly used in diagnosing thyroid dysfunction, using a radioisotope of iodine as the tracer.

### The VA Market: Supply and Demand

**VA Demand.**—The VA and several other agencies purchase nuclear medical equipment through the direct delivery program of the VAMKC's Radiological and Nuclear Equipment and Supplies Division. Nuclear medical equipment accounts for a variable but significant part of total annual VAMKC medical equipment procurement expenditures. In 1979 it accounted for 19 percent of total non-FSS equipment expenditures; in 1980, 12.5 percent; in 1981, 18.1 percent; and in 1982, 6.6 percent. Total expenditures for nuclear medical equipment were $10 million in 1979, $4.3 million in 1980, $5.4 million in 1981, and $8.3 million in 1982 (131,132).

The VAMKC manages direct delivery purchases of nuclear diagnostic equipment for a number of agencies, including the VA, Public Health Service, Army, Navy, Air Force, and other Government agencies. It appears that the VA is not always the largest buyer of nuclear medical equipment through the VAMKC. In 1979 the VA accounted for 81.2 percent of total expenditures on nuclear medical equipment; by 1980 it accounted for only 49 percent of the expenditures, though it was still the largest buyer; and in 1981 the VA accounted for only 32.4 percent of expenditures, buying less than the Army (131). There is no breakdown of equipment purchases by agency in 1982 or 1983.

**VAMKC Procurement Relative to the National Market.**—VAMKC procurement of nuclear medical equipment accounts for a moderately significant part of the national market. In 1982 VAMKC procurement totaled about $8.3 million. Based on the data that nuclear medical equipment vendors must provide the VAMKC, it would appear that VAMKC procurement in that year accounted for approximately 7 percent of these vendors' nuclear medical equipment sales (with a range from about 5 to 10 percent) (132).

**VAMKC Demand Variability.**—VAMKC procurement of nuclear medical equipment has fluctuated from year to year (see table C-3). The variability of nuclear medical equipment expenditures is not as great as those for X-ray equipment, but it is significant.

**Suppliers to the VA Market.**—Companies with VAMKC annual contracts in the past 3 years include (in alphabetical order) Elscint, Inc.; General Electric Co.; MEDX, Inc.; Picker International; Raytheon; Siemens; Technicare; and Toshiba Medical Systems. All major manufacturers appear to have an annual contract with the VAMKC.

It is difficult to assess the competitiveness of the nuclear medical equipment market. The four firms with the largest market shares in 1982 accounted for almost 95 percent of VAMKC procurement, and the pattern is similar in earlier years for which data are available. With such high market concentration, the firms are likely to recognize their mutual dependence, and vigorous price rivalry would not be expected.

However, other factors operating in the nuclear medical equipment market suggest that this simple structural measure may underestimate true competitiveness. First, in this market there is very rapid technological change. In such situations, firms tend to compete very vigorously in both product development and pricing (78). Second, there have been notable changes in the rankings of the top four firms in the VAMKC market (table C-4).

Not only have the rankings of the firms shifted, but as table C-5 shows, so have their market shares. (If the firms were quite close to each other in market shares, there could be significant movement in the firms' rankings without significant shifts in market shares.) Again, the greatest possible sum of the absolute values of market share changes is 200. The data in table C-5 suggest that firms are competing with each other for market share, although, as discussed in the section on X-ray equipment, other explanations are possible.

### Table C-3.—Annual Percentage Change in VA Marketing Center Procurement of Nuclear Medical Equipment, 1979-82

| | 1979-80 | 1980-81 | 1981-82 |
|---|---|---|---|
| Total | −57.5% | +25.9% | +54.8% |
| VA only | −74.3% | −16.7% | N.A. |

SOURCE: U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished data, Hines, IL, 1983; and U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished information from vendors' 1982 contracts, Hines, IL, 1983.

### Table C-4.—Changes in Rankings of Four Largest Sellers of Nuclear Medical Equipment Through the VA Marketing Center, 1979-82

| 1979 | 1980 | 1981 | 1982 |
|---|---|---|---|
| A | B | B | D |
| B | A | D | A |
| C | C | A | C |
| D | D | C | B |

NOTE: The firm with the largest 1979 VA market share is identified as Firm A, that with the second largest 1979 market share Firm B, etc.

SOURCES: U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished data, Hines, IL, 1983; and U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished information from vendors' 1982 contracts, Hines, IL, 1983.

### Table C-5.—Sum of Absolute Values of Year-to-Year Percentage Changes in Vendors' VA Marketing Center Nuclear Medical Equipment Market Shares, 1979-82

| | 1979-80 | 1980-81 | 1981-82 |
|---|---|---|---|
| Sum of absolute values | 14.1 | 40.5 | 35.4 |
| As a percent of maximum possible value (200) | 7.0% | 20.3% | 17.7% |

SOURCES: U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished data, Hines, IL, 1983; and U.S. Veterans Administration, Marketing Center, Radiological and Nuclear Equipment and Supplies Division, unpublished information from vendors' 1982 contracts, Hines, IL, 1983.

The market concentration and market share data point to opposite conclusions about competition in this market. It is impossible, given available data, to assess pricing rivalry in the VAMKC nuclear medical equipment market. However, though it may be difficult to assess the static efficiency of this market, the pace of technological change and improvement in product performance are consistent with high dynamic efficiency.

## NMR Devices

NMR, or as it is also known, magnetic resonance imaging (MRI), is based on the principle that information can be gathered on the composition of tissue through its response to powerful magnetic fields. The basic tool of NMR is an immense and extremely powerful doughnut-shaped magnet that can enclose the patient's entire body. When subjected to magnetic fields, hydrogen nuclei within the patient's body align themselves in parallel ranks, spinning like tops, and wobbling or "precessing," as tops do, around their axes of spin. The patient is then irradiated with a short electromagnetic pulse, which pushes the spinning nuclei over on their sides. When the pulse subsides, the nuclei return to their positions, reradiating in the process some of the energy they had absorbed. Sensitive receivers pick up this electromagnetic echo. The information about the tissue comes from the timing and intensity of the signal, which depend on the amount of fat or water in a tissue and the type of motion of the nuclei. Computers then analyze the signals and display a cross-sectional image of the area studied (1). The techniques used for developing a cross-sectional image are essentially the same as those used in CT scanners, through digital data processing.

The advantage of NMR is that, unlike CT scanners, NMR does not expose the patient to X-rays. NMR may prove useful in diagnosing cancer and in detecting brain abnormalities and possibly heart damage (56).

### Demand and Supply

NMR (or MRI) devices have only recently received approval of the Food and Drug Administration (FDA), and thus are only beginning to be sold commercially. Their cost is expected to be roughly that of CT scanning devices (56) or perhaps higher (86). According to a recent estimate, by August 1984, 93 NMR units were installed within the United States (84). It is widely believed that NMR's potential market is extremely large. One manufacturer's representative estimated that the NMR national market may be as large as $250 million to $300 million a year within 2 or 3 years (42). Given the size of the potential market for NMR devices, a number of manufacturers have entered the field, including General Electric, Philips, Picker, and Technicare.

Through fiscal year 1983 only one NMR device had been procured through the VAMKC, one for a clinical evaluation. This procurement is unlikely to affect the market significantly. Performance specifications were drawn up for the purchase, but they were based on those of available products, and so should not have affected product development (40).

Because NMR's use in medicine is so new and has so recently received FDA approval for clinical use, the market is in its youth. However, NMR will likely have a significant market within a few years. It would clearly be in the public interest for the VAMKC to begin planning its NMR procurement policies.

## PET Devices

PET is another technique for cross-sectional imaging. It is unique in producing images of chemical activity within the body, such as local metabolism. In PET, positron-emitting isotopes of biologically significant atoms—e.g., oxygen, nitrogen, or carbon—are produced using a cyclotron. These isotopes are then attached, or "tagged," to a physiologically active material, such as glucose, and administered to the patient. Finally, a scanner determines the postinjection distribution of the isotope, the information being processed like that in a CT scan to produce a two-dimensional image. The image is significant because the distribution of the isotope reflects the distribution, and therefore the utilization, of the metabolite (75).

### Demand and Supply

PET has attracted attention in the popular press for its potential in diagnosing metabolic disorders, brain abnormalities, and cancer. It would appear to be a way of observing abnormalities in body chemistry, with great medical potential.

At present, however, there does not appear to be a significant market developing for PET scanners. In part, this probably reflects the expense of PET, perhaps $1 million for the PET scanner itself and as much as another $2.5 million for a cyclotron to produce the radioactive isotopes (1).

The VA has purchased two PET scanning devices and apparently has no immediate plans to purchase more, so VAMKC procurement practices have most likely not affected whatever market this product has. It is uncertain whether a market for PET will develop later, but at the moment PET does not appear to be an important issue for procurement planners.

## Ultrasound Diagnostic Equipment

Ultrasound is generally defined as vibrations between 20 kHz and 30 MHz. The sound frequencies used for most diagnostic purposes range from 1 to 12 MHz. Such ultrahigh frequencies are produced by piezoelectric transducers that convert electrical energy to vibratory mechanical energy (sound). After a short sound burst, the transducer circuitry is switched to act as a receiver for returning sound or echoes, and for each pulse of sound emitted the reflectivity of tissue along the line of sound transmission is measured. The returning echo is converted to an electrical signal that is processed and stored in digital form.

In traditional ultrasound the echoes are displayed on an oscilloscope, with the intensity of each echo represented by a correspondingly bright spot on the screen. The position of the echo is displayed in the X-Y plane depending on the position of the transducer and the transit time of the acoustic pulse. In more modern ultrasound equipment, the digitized information can be processed with digital image processing to obtain a better picture of the target object. Moving the sound beam through the tissues by moving the transducer is termed scanning. Using scanning techniques, a series of parallel or orthagonal tomograms, which are images of a slice or plane, can be assembled into a three-dimensional image of an organ.

Ultrasound is extremely useful in diagnosing heart disease and in detecting abnormalities of the liver, kidneys, gallbladder, and lymph nodes in the abdomen (72). It also has the very important attraction of employing nonionizing radiation at low power levels; no harmful effects have been found in humans in almost 30 years of clinical application (72). However, ultrasound has limitations. It requires a soft-tissue path between the transducer and the region of study; intervening bone, air, or dense fat attenuates and distorts the sound (60,72). In addition, ultrasound cannot effectively penetrate deep into tissue (about 22 cm is now the practical limit) and thus cannot effectively analyze problems in blood vessels or other parts deep within the body (77).

## General Demand Characteristics

**Supplies v. Equipment Costs.**—Ultrasound equipment is relatively inexpensive to operate. Costs of supplies and expendables are modest, perhaps at most one-fifth or one-sixth of the equipment's purchase price, according to one industry source (60).

**Equipment Purchase Price.**—Ultrasound equipment varies substantially in price depending on a system's capabilities. A system typically costs between $40,000 and $120,000, in the middle range for the diagnostic medical equipment discussed here.

**Servicing and Technical Support.**—Servicing and technical support are important to the proper functioning of ultrasound equipment. Manufacturers will frequently provide training in these areas to customers' personnel, and service availability is one of the important factors affecting VA procurement of ultrasound equipment (60,85).

## The VA Market: Demand and Supply

**VA Demand.**—Ultrasound equipment has been purchased through the VAMKC's direct delivery program since April 1983. Prior to that it was purchased through decentralized contracts. From March 1, 1980, to February 1981, such ultrasound procurement totaled $6.84 million; from March 1, 1982, to March 31, 1983, VAMKC procurement of ultrasound equipment totaled about $11.5 million; in 1983 it is expected to be about $5 million (85).

Differences in contract, fiscal, and calendar years make it impossible to calculate the proportion of non-FSS medical equipment expenditures accounted for by ultrasound equipment. The $11.5 million spent on ultrasound equipment in the 1982 contract year is equal to about 9 percent of total VAMKC direct delivery equipment procurement costs in the 1982 Government fiscal year. The 1980 contract year ultrasound procurement of $6.84 million is equal to about 20 percent of 1980 fiscal year direct delivery equipment procurement costs, although it was not included in the direct delivery program at the time. The figure for 1983 is likely to be much smaller, perhaps 5 to 10 percent (85,131,132). Exact data are not available, but according to the VAMKC contract specialist for ultrasound, the VA accounts for about 60 percent of total VAMKC procurement of ultrasound equipment, with the Army, Air Force, and Public Health Service accounting for most of the rest (85).

**VA Demand Relative to the National Market.**—The VA accounts for a very small proportion of the national demand for ultrasound equipment. Several sources estimated that national sales of ultrasound equipment in 1982 were about $400 million (60,74). Assuming VA procurement to be 60 percent of VAMKC procurement, VA expenditures represent not even 2 percent of the national market; VAMKC procurement altogether was probably not more than 3 percent. National sales of ultrasound equipment are expected to be less in 1983 than in 1982, about $285 million. However, VAMKC ultrasound procurement is expected to fall even more, to about $5 million, or less than 2 percent of the market. Although VAMKC procurement may account for a larger proportion of some vendors' sales than this, no vendor indicated on its annual contract that VAMKC procurement accounted for more than 5 percent of the company's ultrasound equipment sales (85).

**VAMKC Demand Variability.**—VAMKC ultrasound procurement expenditures vary substantially from year to year. The decline from contract year 1982 to contract year 1983, for example, is expected to be greater than 55 percent. More than half the manufacturers' representatives interviewed indicated that VAMKC demand variability is greater than that of most private customers (55,60,74,87).

**Suppliers to the VA Market.**—The capital requirements to enter the ultrasound market are smaller than for many other kinds of diagnostic medical equipment, and many small companies have entered the market in recent years. This is reflected in the VAMKC market, where more than 15 companies will have annual contracts this year (85).

Although some companies do specialize in particular ultrasound applications (abdominal, cardiac, etc.) there appears to be substantial competition in the market. In contrast to the VAMKC's procurement of other kinds of medical equipment discussed here, its procurement of ultrasound equipment is very evenly distributed among the vendors on contract. The four vendors with the largest shares of the VAMKC market accounted for only slightly more than half of the VAMKC market in 1982; sales of the vendors ranked seventh and eighth totaled almost as much as those of the vendor with the largest share; and even the low-ranked vendors accounted for significant shares of the VAMKC market (85). Consistent with this low market concentration, the relative ease of entry into the market, and the industry's very rapid technological change, the ultrasound equipment market was described by the VAMKC contract specialist as "fiercely competitive" (85).

## Electromedical Equipment

The 5-digit SIC category Electromedical Equipment (SIC Code 36932) includes a wide variety of diagnostic, therapeutic, and patient monitoring equipment. In this discussion, VA procurement of electrocardiograph (ECG), electroencephalograph (EEG), and patient monitoring equipment is examined.

In electrocardiography, electrodes attached to the chest and extremities measure changes in the electrical potential of the body's surface, which are associated with the electrical activity accompanying the action of the heart. Thus, such measurements can detect heart abnormalities. In electroencephalography, electrodes attached just under the scalp detect electrical activity in the brain. EEG recordings are used in diagnosing epilepsy, stroke, tumors, and other brain abnormalities. ECG and EEG recordings were originally made on paper rolls (63), but digital recording techniques are replacing the old recordings, so that ECG and EEG equipment can easily be used in patient monitoring as well as diagnosis.

Patient monitoring equipment is used to monitor parameters reflecting a patient's medical condition, such as blood pressure, pulse, brainwave activity, temperature, and respiration. Modern patient monitoring equipment is based on semiconductor chip technology, and often incorporates microcomputer components. Patient monitoring equipment varies in complexity and cost, from stand-alone units that monitor one or a few functions for a single patient to central station systems that can monitor a wide range of physiological indicators for a very large number of patients and transmit the data for display to a single location, such as a nurses' station (20).

### General Demand Characteristics

**Equipment Purchase Price.**—Stand-alone EEG, ECG, and patient monitoring units range from $2,000 to $16,000, while systems can cost anywhere from $20,000 to several hundred thousand dollars depending on their size and complexity (20).

**Servicing and Technical Support.**—According to an industry source, most EEG, ECG, and patient monitoring equipment does not require much servicing, and the annual cost of a full-service contract is about 5 to 10 percent of the equipment's purchase price.

### The VA Market: Demand and Supply

**VA Demand.**—Patient monitoring systems are purchased through the VAMKC direct delivery program; stand-alone monitoring units and EEG and ECG equipment are purchased through the FSS program.

In July 1982 the responsibility for procurement of patient monitoring systems was transferred within the VAMKC. Unfortunately, the procurement data were not similarly transferred, and it was not possible to construct a historical series for this kind of equipment. In addition, according to VAMKC personnel, FSS procurement data for stand-alone EEG, ECG, and patient monitoring equipment are also not readily available for 1981 and 1982 (49).

FSS procurement of such stand-alone equipment during the first three quarters of the 1983 contract year (beginning August 1982) totaled $4.6 million (49). Assuming that this figure can be extrapolated for the year (multiplying it by four-thirds), annual FSS procurement during the contract year should be about $6.2 million.

In fiscal year 1982 (beginning October 1981), VAMKC procurement of patient monitoring systems under the direct delivery program totaled $12.2 million, which suggests that expenditures for such systems are about twice those for stand-alone equipment. In the same year, procurement of patient monitoring systems represented close to 10 percent of total equipment procurement under the direct delivery system (132). The lack of data makes it impossible to calculate corresponding figures for earlier years.

**VAMKC Procurement Relative to the National Market.**—According to one industry source, the national market for patient monitoring systems is about $220 million, and that for stand-alone EEG, ECG, and patient monitoring units about $100 million (20). If the VAMKC figures of $6 million for stand-alone equipment purchases and $12 million for monitoring system purchases are in fact representative, then VAMKC procurement accounts for about 5 to 6 percent of national sales for both categories of equipment. Because the data are incomplete, and because VAMKC procurement of other medical equipment varies greatly from year to year, it is best to consider these estimates as rough ones.

**Suppliers to the VA Market.**—Although a number of firms produce patient monitoring equipment, the VAMKC market is dominated by a few large firms. In fiscal year 1982, the four firms with the largest shares of VAMKC direct delivery procurement accounted for close to 95 percent of such procurement, and a single firm accounted for much of the 95 percent (132). The national market for patient monitoring equipment is also highly concentrated. Some companies appear to have a much higher share of the VAMKC direct delivery market than they do of the national market, while for other companies the reverse is true. Based on information in 1982 annual contracts, one vendor's share of the direct delivery market was only 7 percent of its share of the national market, while another vendor's direct delivery market share was almost seven times as large as its national market share. This is a puzzling phenomenon, and to understand it would require a closer investigation than is possible here; however, since it may reflect some positive or negative feature of procurement rather than chance, it may warrant further study.[4] It was not possible, given available date, to calculate the market concentration of the FSS patient monitoring equipment market.

Despite the apparent market concentration and the existence of a dominant firm, Hewlett-Packard, both the VAMKC and industry sources characterized the firms in the patient monitoring equipment market as very competitive (20,47,49,92).

## Hemodialysis Equipment

Dialysis is the transfer of solute (a dissolved substance) across a semipermeable membrane. Hemodialysis, through "artificial kidney" machines, is dialysis to purify the blood of people whose kidneys have partly or completely ceased to function. In such machines, blood is circulated on one side of a semipermeable membrane while a special dialysis fluid is circulated on the other. The dialysis solution must closely match the chemical composition of the blood. Metabolic waste products, such as urea and creatinine, diffuse through the membrane into the dialysis fluid and are discarded, while substances needed by the body (e.g., sodium chloride) are prevented from diffusing by including the same substances in the dialysis fluid (63).

### The VA Market: Demand and Supply

**VA Demand.**—Manufacturers contract with the FSS division of the VAMKC to provide hemodialysis equipment and supplies to Government agencies at specified prices. These prices, along with product descriptions, provide the supply schedules that VA hospitals and other Government agencies use to order equipment and supplies directly. Most schedules are so-called multiple award schedules, specifying several different vendors' versions of an item so that buyers can choose among them. Multiple award schedules are governed by a most favored customer clause (described later below). Less frequently, the FSS program awards contracts through competitive bidding and makes a single award (47).

The VA spends a relatively modest sum on hemodialysis equipment relative to its expenditures on hemodialysis disposables and supplies. One manufacturer estimated that in the national market equipment costs are only 5 to 8 percent of total dialysis costs, with disposables, consumables and personnel costs accounting for the remainder (17).

According to the FSS Solicitation for Offers for 1984, estimated expenditures for hemodialysis equipment for 1984, which are based on actual 1983 expenditures, are slightly under $650,000 (129), or about one-half of 1 percent of total annual VAMKC equipment procurement expenditures. This figure seems unrealistically low. At approximately $7,000 per machine (the price quoted by two manufacturers), the VA would have purchased only 93 machines. However, the VA now has about 1,900 machines in use, and the average machine is replaced after 5 years; this implies a 20-percent turnover rate (17) and thus that the VA should be buying about 400 machines annually. In estimates of the VA's importance in the national market, it will be assumed that a normal annual procurement is between 10 and 20 percent of stock or 200 to 400 hemodialysis machines per year. If this is the case, then annual expenditures on hemodialysis equipment are between 1 and 2 percent of total annual medical equipment procurement.

**VA Demand Relative to the National Market.**—There are approximately 25,000 hemodialysis machines in use in the United States today; of these, about 1,900, or 7.6 percent, are in use in VA installations.

The market for new machines is a function of depreciation and obsolescence of existing equipment and the growth of new facilities. More than one manufacturer estimated that the size of the national market was about 4,000 to 5,000 machines per year at an average unit price of between $7,000 and $8,000, or between $28 million and $40 million (17,73). If FSS procurement of hemodialysis equipment is roughly proportional to its share of dialysis equipment now in use, then it should account for about 7 to 8 percent of the national market. It is probably safe to say that FSS procurement represents between 5 and 10 percent of the national market.

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[4] One possible explanation is that VA hospitals are generally larger, university-affiliated hospitals. Certain vendors do better in this select market than they do elsewhere (10).

**Suppliers to the VA Market.**—The national market for hemodialysis equipment is highly concentrated; the three largest companies account for about 90 percent of total market sales, and only five firms account for virtually all the national sales. Data are not available to calculate manufacturers' market shares of the VAMKC FSS market, but sales in this market appear as highly concentrated as in the national market (17,73,135).

## Analysis and Implications for Policy

### The Importance of VA Procurement in the National Market

The VA's proportion of the national market for medical equipment, considered in isolation, is a misleading measure of the market leverage that the VA exerts. VA procurement is channeled through the VAMKC, which also acts as contract negotiator and administrator for the Public Health Service, the armed services, and other Government agencies. The combined procurement of all these groups, then, determines the buying power of the VA. As a result, the rest of this discussion will consider all VAMKC procurement, rather than its procurement for the VA alone.

VAMKC procurement accounts for a significant, but not overwhelming, proportion of the national market for most types of equipment examined in this appendix; in some of the markets, the VA proportion is very modest. Based on data in VAMKC annual contracts, VAMKC procurement accounts for 5 to 10 percent of the national markets for X-ray, nuclear diagnostic, and hemodialysis equipment, about 5 percent of the national market for EEG, ECG, and patient monitoring equipment, 3 percent of the national market for CT scanning equipment, and 1 to 2 percent of the ultrasound equipment market. The VAMKC share of the national market for digital image processing equipment is uncertain, but most likely is very small (40,131,132). Thus, although the dollar amounts of VAMKC procurement may be significant, and vendors are certainly anxious to maintain their VAMKC market share, VAMKC procurement does not dominate any market examined here.

### Conditions of Supply

Numerous structural characteristics of the market can be said to shape observed market outcomes (78), but only a few of the most important will be discussed here.

### Barriers to Entry

For some of the equipment categories examined, particularly CT scanners and radiographic and nuclear diagnostic systems, the capital requirements of the market appear to preclude the entry of small firms. The servicing and technical support of some products are so important that the firms that cannot offer well-organized nationwide support suffer a severe disadvantage.

Of course, all these markets are not entirely closed to small firms. There is enormous technological change occurring in almost all the markets examined, much of it in computer applications to diagnostic medicine, and in software rather than hardware. In such markets, a small firm can succeed if it finds a niche. (On the basis of reports of mergers and acquisitions, the result of that success is often being purchased at an attractive price by a larger firm in the medical equipment market.)

### Market Concentration

Market concentration, the proportion of sales accounted for by the largest sellers in a particular market, is quite high in almost all the medical equipment markets examined here. In the VAMKC markets for X-ray, nuclear diagnostic, patient monitoring, and hemodialysis equipment, the four largest firms in each class accounted for 90 to 95 percent of procurement expenditures within their classes. Procurement of CT scanners has been based on competitive bids, and the same firm won the contract in both major bids. Only in the market for ultrasound equipment are VAMKC procurement expenditures spread more evenly over a large number of companies. Generally, such high market concentration is associated with a lack of high pricing rivalry, but it is not clear that this is the case for the industries examined here.

### Market Share Instability

High market concentration can sometimes be a misleading indicator of firms' conduct in the market. In both the X-ray and nuclear diagnostic equipment VAMKC markets, market share instability suggests that rivalry among the firms is greater than would be predicted on the basis of market concentration.

## Summary of Competitive Conditions

Although the medical equipment markets examined in this appendix certainly do not conform to the picture of perfectly competitive markets, the volatility of market shares and the very rapid pace of technological change suggest that these markets still function competitively. In a few cases, rivalry may be based more on product performance than price. Two of the VAMKC markets, for ultrasound diagnostic and patient monitoring equipment (the first of which is highly concentrated and the second not), were both described by VAMKC personnel as extremely competitive (49).

## The Impact of VAMKC Procurement on Vendor Pricing

The impact of VAMKC procurement on market outcome depends not only on supply conditions and the level of VAMKC procurement, but also on the procedures and policies that govern VAMKC procurement, the most important of which are analyzed below.

**Brand Name Justification.**—When a VA hospital is authorized to buy equipment, the VAMKC forwards to the hospital a list of suppliers on contract whose equipment meets the specifications of the purchase order, ranked by order of cost. By regulation, the hospital is required to buy from the least-cost supplier unless it can justify purchasing from a different source (e.g., service availability). This requirement is called brand name justification. Because suppliers are anxious to maintain their share of the VAMKC market, the requirement almost certainly lowers prices.

**Firm Fixed Price Clause.**—Under the terms of a VAMKC contract, suppliers cannot increase prices during the contract year. Furthermore, if they lower the price at any time during the year, the lower price holds for the remainder of the year. The firm fixed price clause may or may not result in lower procurement costs. Suppliers offer temporary price discounts in the private market to promote their products. Normally, promotional offers would probably be extended to the VAMKC as well, but because of the firm fixed price clause, suppliers are reluctant to make them. Even the requirement that prices not be increased during a contract year has indeterminate effects on procurement costs. While the requirement does protect those who buy through the VAMKC from price increases, suppliers may charge a higher price at the start to ensure a profit. Altogether, it is extremely difficult to determine the net effect of the firm fixed price clause.

**Public Disclosure Requirements.**—By law, the public has access to VAMKC procurement prices for medical equipment. Both theoretical and empirical evidence support the view that this results in higher procurement costs for the VAMKC. First, a firm's benefits from cutting its price are in part a function of the so-called retaliation lag, the length of time before rivals learn of the price cut and cut their own prices in response. Price disclosure requirements reduce the retaliation lag, and therefore discourage price cutting in the VAMKC market. Because other buyers of medical equipment also have access to the price data, the VAMKC price may be the private buyer's target in pricing negotiations, which can also inhibit price cutting in the VAMKC market. Finally, suppliers of X-ray, nuclear medical, patient monitoring, and hemodialysis equipment have stated that the prices offered to the VAMKC are higher because of the contract disclosure requirement. Some suppliers said the disclosure requirement did not affect pricing in their markets, for the reason that pricing information was widely available from other sources.

**No Volume Commitment.**—Having a contract with the VAMKC does not imply any contractual volume commitment in procurement. For two equipment categories, X-ray equipment and nuclear diagnostic equipment, volume commitment does not appear to be an important consideration. For the other equipment categories examined here, volume is a major influence on pricing.

There are two likely reasons why volume commitment would be unimportant in some industries and very important in others. First, when equipment is purchased from stock, and is fairly standardized, a volume commitment can reduce manufacturing costs that can be passed on to the buyer, but not when the equipment is custom made. Second, the effects of volume commitments seem to depend on whether equipment is expensive or inexpensive. When equipment is inexpensive, the costs of preparing contracts and marketing are higher relative to the purchase price of the equipment. In this situation, the savings that come with volume commitment are more significant. Some suppliers indicated that they might lower their prices by 5 to 10 percent in exchange for a volume commitment. One supplier in the ultrasound market, stated that a purchase of even 15 to 20 units would suffice for a larger price discount than is now offered the VAMKC.

**Most Favored Customer Clause.**—Under the terms of a VAMKC contract, suppliers are prohibited from selling their equipment under a "like contract" to any private buyer at a price lower than that offered the VAMKC. If a lower price is offered to a private buyer, this price must be given to the VAMKC for the rest of the contract year. This stipulation helps ensure that the VAMKC's clients benefit from any vendor competition in the private market.

Although the strictness with which the most favored customer clause is interpreted varies from one equipment category to the next, it almost certainly reduces VAMKC equipment procurement costs. In a few markets, private buyers are offered lower prices than the VAMKC when they make contractual volume commitments, on the grounds that these are not "like contracts," and the effect of the clause is obviously less in those markets. The most favored customer clause can greatly influence private buyers, as discussed below.

**Informal Procedures.**—VAMKC personnel said they were reluctant in practice to purchase mixed medical equipment systems, those in which items of different manufacturers are interconnected. The most important reason for this is the difficulty of assigning financial responsibility for repairs under warranty, in addition to that of determining responsibility for actually making the interconnections. Unfortunately, this VA policy may practically eliminate many smaller companies in procurement, causing higher initial procurement costs. The reluctance to purchase mixed systems is based on experience, but the value of this policy should be reviewed periodically.

## The Impact of VAMKC Procurement on Vendor R&D

In contrast to prosthetic devices, which veterans may have special needs for and the VA has actively developed and procures with great leverage, the categories of medical equipment examined here are ones that the VA and VAMKC affect relatively little. Of the various VAMKC procurement mechanisms that could influence vendors' research and product development, only three seem to exert any significant impact, and of the three, one type is rather indirect.

**Specifications.**—The VAMKC can and does influence product development through specifications. These are often developed from industry standards or based on the characteristics of products already on the market. To maintain their share of the VAMKC market, firms must produce equipment that satisfies the specifications, and some vendors in the markets for X-ray equipment, nuclear diagnostic equipment, CT scanning devices, and patient monitoring equipment stated that they altered their products to meet the requirements (though most of these equipment modifications are incremental changes in performance, not fundamental improvements in product design). Different manufacturers' products have different strengths. It is a great advantage for a manufacturer to have VAMKC equipment specifications "written to its own machine," as discussed below.

**Product Evaluations.**—The VAMKC's Testing and Evaluation Staff evaluates some medical equipment and supply items and makes the results available to the public. According to the director of this program, these results are heavily used (66). It is impossible to quantify the effect of this program on manufacturers' development activities, though no doubt there is some.

**Indirect Effects.**—Within the limitations determined by its shares of the various medical equipment markets, VAMKC procurement can encourage manufacturers' R&D to the extent that it embraces new technologies. For the most part, vendors characterized VAMKC procurement as moderately progressive in this regard. The VAMKC has a policy of not purchasing equipment that is not commercially available and already in clinical use. Thus, VAMKC procurement is not "state of the art" in most instances. However, the fact that most VA installations do attempt to have up-to-date equipment probably has some small positive impact on the profitability, and therefore the extent, of manufacturers' R&D.

## Effects of VAMKC Procurement on Private Buyers

VAMKC procurement practices may affect private buyers of medical equipment in several ways. The most important of these are its information on product evaluations and prices, and the most favored customer clause.

**Product Evaluation Information.**—As mentioned above, the product evaluation information produced by the VAMKC's Testing and Evaluation Staff is extensively used. It must be assumed that the availability of such information leads to better informed medical equipment procurement by private buyers.

**Availability of Price Information.**—There is clear evidence that the price information available from VAMKC annual contracts and bids has sometimes influenced private buyers of medical equipment. A procurement director for a large, private, centrally managed hospital group stated that in one case, he "insisted on a better deal because the VA got a better deal." At the very least, the VAMKC price may be the target for private buyers of medical equipment.

**Most Favored Customer Clause.**—In contrast to the effects of available product evaluation and price information, the most favored customer clause increases the prices that private buyers must pay for medical equipment. Interviews with both vendors and buyers indicated that the clause affects prices of X-ray, nuclear diagnostic, ultrasonic, patient monitoring, and CT scanning equipment. One private buyer indicated that the most favored customer clause was a "major problem" for him. Even when vendors offer lower prices to buyers who make volume commitments, the effect of the VAMKC is still felt.

The most favored customer clause limits price discounting in the private market. For this reason, although the stipulation may lower VAMKC procurement expenditures, it may actually raise Federal health care expenditures through its effect on the equipment and supply costs of private providers of health care. The Federal Government's role in financing health care extends far beyond the agencies that procure medical equipment and supplies through the VAMKC, and if the most favored customer clause increases equipment costs for private buyers who are reimbursed on the basis of costs, it could increase rather than decrease total Federal health care expenditures.

## Manufacturers' Views of VAMKC Procurement

Manufacturers generally demonstrate a positive view of VAMKC procurement. Other than the failure to make volume commitments, which was discussed above, only three issues were identified as clearly problematic: contract documentation requirements, the delay in processing procurement orders, and the problem of "tailored specifications."

**Contract Documentation Requirements.**—Contract documentation was the major complaint of many vendors, especially those of less expensive products, for whom documentation costs are more significant relative to equipment purchase prices. Documentation may also be a greater source of dissatisfaction among smaller firms because larger firms are more likely to have employees specializing in Government accounts. Several manufacturers suggested that the VAMKC maintain a central computer file for contract documentation and simply have vendors update the file when necessary, rather than supply full documentation repeatedly.

**Delay in Processing Orders.**—The time required for the VAMKC to process orders was a major source of irritation for some manufacturers. Apparently, the delays are important only for firms that normally sell their equipment from stock. When manufacturers produce equipment to order, the order typically becomes part of the order backlog (unless the market is extremely slack). In this situation, the time necessary for processing the order is absorbed easily and does not cause problems. When equipment is sold from stock, however, the order can usually be filled immediately, and, as a result, the bureaucratic delay is a major irritation. It is not clear what can be done to alleviate this problem, except perhaps to computerize the procurement process more.

**Tailored Specifications.**—As mentioned above, different manufacturers' products tend to have different areas of strength. When equipment specifications are written to the specifications of a particular manufacturer's product, essentially as "tailored specifications," other manufacturers are at a distinct disadvantage in the VAMKC market. A number of manufacturers from a variety of equipment markets complained of this problem, suggesting that it warrants greater attention from VAMKC personnel. If specification requirements can be prepared with attention to their impact on the number of vendors able to compete, procurement costs may be reduced without significant sacrifice in quality of care.

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